**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| In re: NEURONTIN MARKETING AND SALES PRACTICES LITIGATION | MDL Docket No. 1629<br><br>Master File No. 04-10981<br>Judge Patti B. Saris |
| THIS DOCUMENT RELATES TO: | |
| THE GUARDIAN LIFE INSURANCE COMPANY OF AMERICA v. PFIZER INC., 04 CV 10739 (PBS) and<br><br>AETNA, INC. V. PFIZER INC., 04 CV 10958 (PBS) | |

**FIRST COORDINATED AMENDED COMPLAINT**

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Plaintiffs, The Guardian Life Insurance Company of America ("Guardian"), Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, and Aetna, Inc. ("Aetna") (collectively, "Plaintiffs"), bring this lawsuit against defendants Pfizer, Inc. ("Pfizer"), Warner-Lambert Company and Parke-Davis, a division of the Warner-Lambert Company (collectively referred to as "Parke-Davis" or "Defendants"). The facts and information averred herein are based upon Plaintiffs' personal knowledge and beliefs and upon investigation of counsel. In support of this Amended Complaint against Defendants, Plaintiffs allege the following:

## I. NATURE OF THE CASE

1. This civil action is brought by the Plaintiff third-party payors based on payments they made for the prescription drug Neurontin® ("Neurontin"), an epilepsy drug that reportedly earned Defendants over $2.7 billion in worldwide sales in 2003.

2. From 1994 to the present, Defendants created and implemented a fraudulent marketing and sales scheme that misrepresented the scientific, medical and clinical data that related to the safety, medical efficacy, effectiveness and usefulness of Neurontin for medical conditions other than as an adjunct therapy for epilepsy, which was the only use approved by the United States Food and Drug Administration (the "FDA") in 1994. The purpose of the scheme was to substantially increase the sales of Neurontin and reap unlawful profits at the expense of healthcare insurers, consumers and others. Defendants systematically, between themselves and with other entities and individuals, created a pervasive, fraudulent and unlawful system to cause insurers and individual patients to pay for Neurontin to treat a variety of symptoms for which Neurontin had not received approval from the FDA (so called "off-label" uses), and for which the drug was not proven to be safe, medically efficacious, effective or useful. Using a cadre of physicians and intermediary medical marketing firms, and their own employees, Defendants

aggressively marketed and sold Neurontin to treat a multitude of medical conditions – ranging from treatment for bipolar disorder to treatment for anxiety – despite Defendants' knowledge that there was no credible scientific basis to support such uses. Defendants' scheme targeted health insurers, patients and others. Defendants knew that once a physician prescribed Neurontin, the substantial drug sales that Defendants sought were dependent upon third-party payors, such as Plaintiffs, covering the cost of the drug or purchasing and dispensing the drug to plan members. Plaintiffs paid for Neurontin in quantities far exceeding its warranted use, and these vast quantities (and resulting revenues for Defendants) were the result of Defendants' fraudulent scheme.

3. Defendants' deceptive marketing and sales practices included, *inter alia*: (a) deliberately misrepresenting the scientific, medical and clinical data that related to the safety, medical efficacy, effectiveness and usefulness of Neurontin for medical conditions other than as an adjunct therapy for epilepsy; (b) deliberately misrepresenting the credentials and qualifications of certain of Defendants' employees as purported specialists, medical researchers, physicians and scientific employees in order to market and sell Neurontin for off-label uses; (c) wrongfully interfering with the physician-patient relationship by compensating physicians for prescribing Neurontin for off-label uses; (d) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and the authors of the articles, studies and reports; (e) organizing seminars and events encouraging physicians to prescribe Neurontin for uses knowing such uses were not proven to be safe, medically efficacious, effective or useful; and (f) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of seminars, events, articles and publications aimed to sell Neurontin to off-label markets.

4. Defendants' reaped skyrocketing financial returns from the wrongful scheme. In 1995, Defendants' revenue from the sale of Neurontin was $97.5 million; by 1997, sales increased to $292 million; by 1999, sales increased to $913 million; by 2000, sales increased to more than $1 billion; and by 2003, worldwide sales of Neurontin reached nearly $2.7 billion. This dramatic increase in sales – approximately 50% per year – was fueled almost entirely by prescriptions for off-label uses and was the direct result of Defendants' fraudulent marketing scheme. For example, in 1996, 50% of Neurontin's sales were attributable to off-label uses, in 2000, more than 78% of the Neurontin prescriptions written were for off-label uses, and by 2003, 90% of all Neurontin prescriptions were for off-label uses.

## II. PARTIES

5. Guardian is a mutual life insurance company organized and existing under the laws of the state of New York. Guardian provides health payment benefits to approximately 1.3 million people in all fifty states and have agreements with thousands of participating pharmacies in the United States. From 1994 to the present, Guardian paid tens of millions of dollars to U.S. pharmacies for illegitimate off-label uses of Neurontin caused by Defendants' wrongful acts.

6. Kaiser Foundation Health Plan, Inc., a not-for-profit corporation with its headquarters in Oakland, California, is among the largest health maintenance organizations in the United States. As of December 2004, Kaiser Foundation Health Plan, Inc. had 8.2 million members in nine states and the District of Columbia, with over 6 million members in California. The remaining members are in Colorado, Georgia, Maryland, Virginia, Oregon, Washington, Hawaii, Ohio and the District of Columbia. Kaiser Foundation Health Plan, Inc. offers its members pharmacy benefits that include coverage of Neurontin. Kaiser Foundation Health Plan, Inc. owns and operates its own in-house pharmacies in the same nine states in which it has members and the District of Columbia. These pharmacies purchase prescription drugs, including

Neurontin, and dispense these drugs directly to Kaiser Foundation Health Plan, Inc. members. A limited number of health plan members purchase their prescription drugs through a pharmacy benefit manager retained by Kaiser Foundation Health Plan, Inc. From 1994 to the present, Kaiser Foundation Health Plan, Inc. paid tens of millions of dollars for illegitimate off-label uses of Neurontin caused by Defendants' wrongful acts.

7. Kaiser Foundation Hospitals is a not-for-profit California corporation which owns and operates thirty hospitals in California, Oregon and Hawaii and contracts with Kaiser Foundation Health Plan, Inc. to provide or arrange for hospital services for Kaiser Foundation Health Plan, Inc. members in each state in which Kaiser Foundation Health Plan, Inc. operates. From 1994 to the present, Kaiser Foundation Hospitals paid tens of millions of dollars for illegitimate off-label uses of Neurontin caused by Defendants' wrongful acts.

8. Aetna is a Pennsylvania corporation with its principal place of business in Hartford, Connecticut. Aetna and its subsidiaries provide health payment benefits to more than 13 million people in virtually every state and territory of the United States and have agreements with tens of thousands of participating pharmacies in the United States. From 1994 to the present, Aetna paid tens of millions of dollars to U.S. pharmacies for inappropriate off-label prescriptions of Neurontin for Aetna members in every state in the United States, the District of Columbia and the Commonwealth of Puerto Rico.

9. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is principally engaged in the manufacture and sale of pharmaceuticals and is one of the largest pharmaceutical companies in the world.

10. Defendant Warner-Lambert Company was acquired in June 2000 by Pfizer. This acquisition included Warner-Lambert's Parke-Davis division. Prior to the acquisition, Warner-Lambert was a Delaware corporation with its principal place of business at 201 Tabor Road, Morris Plains, New Jersey. In 1993, Warner-Lambert received FDA approval to market Neurontin in the United States as an adjunct therapy for epilepsy and did so through its Parke-Davis division. After the acquisition, the marketing of Neurontin continued to be managed at the merged companies' Morris Plains, New Jersey location. In May 2002, Pfizer obtained FDA approval for Neurontin to treat postherpetic neuralgia (pain resulting from shingles of herpes zoster) in adults. Adjunctive epilepsy therapy and postherpetic neuralgia are the only two indications for which Neurontin has been approved by the FDA.

## III. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over all of the Coordinated Complaints herein pursuant to 28 U.S.C. § 1331 because the claims in this action arise under the laws of the United States; and pursuant to 18 U.S.C. § 1964 because this Court has jurisdiction to prevent and restrain violations of 18 U.S.C. § 1962 (RICO); and pursuant to 28 U.S.C. § 1367(a) because this Court has supplemental jurisdiction over all non-federal clams in this action that form part of the same case or controversy as those within the Court's original jurisdiction.

12. This Court has subject matter jurisdiction over Plaintiffs Aetna, Kaiser Foundation Health Plan Inc. and Kaiser Foundation Hospital pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship and the amount in controversy exceeds $75,000, exclusive of interest and costs.

13. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over the violations of the Uniform Deceptive Trade Practices Act statutes, Pennsylvania Insurance Fraud Statute, and Plaintiffs' allegation of unjust enrichment.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), and 18 U.S.C. § 1965.

## IV. FACTUAL ALLEGATIONS

### A. Neurontin

15. New pharmaceutical drugs may not be marketed in the United States until the sponsor of the pharmaceutical has proven to the FDA that the drug is safe and effective for specific indications at specified dosages. 21 U.S.C. § 355(b); 21 C.F.R. § 310.3(h)(f). The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA. Although it is not unlawful for physicians to prescribe approved drugs for indications or at dosages different than those set forth in a drug's labeling (referred to as "off-label" use), the Food, Drug, and Cosmetic Act generally prohibits drug companies from marketing or promoting approved drugs for uses other than those set forth in the drug's approved labeling. 21 U.S.C. § 355(b). Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition against commercializing off-label uses. This regulatory scheme protects patients and consumers by insuring that pharmaceutical companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body.

16. Pfizer currently markets and sells Neurontin, a brand name prescription drug composed of the chemical compound (1-aminomethyl)-1-cyclohexaneacetic acid, generically known as gabapentin. On December 30, 1993, Neurontin was approved by the FDA for use as an "adjunctive therapy" in the treatment of partial seizures with and without secondary generalization in adults with epilepsy in doses from 900 to 1800 milligrams per day. Adjunctive therapy means that the drug cannot be prescribed by itself for the treatment of epilepsy -- it is to be used in combination with another front line epilepsy drug. The FDA did not find Neurontin to be safe and

effective as a "monotherapy" -- a single drug treatment for epilepsy. The drug sponsor, Defendant Warner-Lambert, did not seek FDA approval in 1993 for any medical condition other than epilepsy.

### B. Defendants' Deliberate Decision to Avoid Seeking FDA Approval and Promote Off-Label Uses for Neurontin Through the Publication of False and Misleading Scientific, Medical and Clinical Data

17. At the time Neurontin was approved by the FDA in 1993, Defendants knew that the market for adjunctive therapy for epilepsy was relatively small with a population potential of approximately two million patients. In fact in May 1994, Defendants estimated that Neurontin's ultimate sales potential was $500 million *over the lifetime of the drug*. Defendants also knew that the FDA prohibited drug manufacturers from promoting and marketing their drugs for uses not approved by the FDA. Accordingly, the fraudulent scheme devised by Defendants not only misrepresented the scientific data regarding Neurontin, but also misrepresented the creator and promoter of that information.

18. In the late 1980s and early 1990s, Defendants considered other potential uses for Neurontin besides epilepsy. Defendants filed several patent applications for Neurontin as a treatment for depression, neurodegenerative disease, mania, bipolar disease and anxiety. Notwithstanding the claims made in their patent applications, however, Defendants chose not to seek FDA approval for these indications or start the internal process within Parke-Davis to obtain approval for these uses. Senior product managers at Parke-Davis viewed Neurontin as a niche drug and advised the corporation lower its expectations regarding the ultimate sales potential for Neurontin.

19. Despite that earlier view, in October 1994, the Neurontin Development Team, a group of high-level officials at Parke-Davis in charge of clinical research, patents, regulatory, marketing and manufacturing issues, began to consider whether Parke-Davis should attempt to

extend Neurontin's use to psychiatric disorders, a market significantly larger than epilepsy. Other anticonvulsant drugs had been used for (and FDA-approved for) psychiatric disorders, including bipolar disorder, panic disorder, post-traumatic stress disorder and possibly personality disorders. Defendants knew, however, that there was no scientific rationale supporting Neurontin's safety or effectiveness for these psychiatric uses because Neurontin has a different mechanism of action from other anti-epileptics.

20. In January 1995, Parke-Davis's Marketing and Planning Department presented a preliminary market analysis to the Neurontin Development Team for Neurontin's use for psychiatric indications. Without considering whether the drug could be proven to be safe or effective for such uses, the report viewed the market as very favorable for Neurontin. At the same Neurontin Development Team meeting, the possibility of expanding the market for Neurontin's use for pain syndromes, another market substantially larger than epilepsy, was also discussed.

21. In February 1995, the New Product Committee ("NPC") informed the Neurontin Development Team that it supported the development of Neurontin for other indications and asked for a formal proposal. John Boris was instructed to prepare market feasibility analyses of new potential indications, including bipolar disorder, generalized anxiety disorder, social phobia, neuropathic pain and migraine prophylaxis.

22. In March 1995, a senior scientist in Parke-Davis's Research Department informed the Neurontin Development Team that bipolar disorder may not be a good area to pursue for regulatory approval because of the short patent exclusivity period (the patent on Neurontin was set to expire in December 1998) and the difficulty and expense in conducting the necessary clinical studies in order to demonstrate whether the drug was safe and effective to treat bipolar disorder. The Development Team, however, considered simply publishing scientific, medical and clinical

data regarding the safety and medical effectiveness and usefulness of Neurontin for psychiatric uses including bipolar disorder. Certain members of Parke-Davis's Regulatory Department opposed the pursuit of a "publication strategy," stating that seeking FDA approval for bipolar disorder through appropriate clinical studies was the correct way to proceed. That recommendation was not followed.

23. On March 22, 1995, the Parke-Davis Marketing Council met in Lyons, France, and recommended that Parke-Davis pursue a "publication strategy" instead of following the formal regulatory approval channels with regard to psychiatric indications for Neurontin. Thus, given the relatively short period of patent protection, Parke-Davis chose to avoid the costly and thorough process of seeking FDA approval, and instead, directly and immediately set out on a mission to persuade the healthcare field to use Neurontin to treat off-label conditions through a myriad of fraudulent acts. Members of the Marketing Council included the then-President of Parke-Davis, Tony Wild, and other senior management.

### C. Implementation of the "Publication Strategy" and Creation of the Promotion Enterprise

24. In May 1995, a formal Parke-Davis Marketing Assessment report recommended that the company implement this publication strategy for various psychiatric indications. The report predicted that the revenues generated by sales for these indications would justify investment in the publication strategy. The report, however, specifically noted a lack of scientific rationale for Neurontin's use for bipolar disorder, since Neurontin has a different mechanism of action from other anti-epileptics. This crucial distinction also made Neurontin suspect for treating acute mania, social phobia and panic disorder since its use for those conditions rested on the same rationale for using Neurontin to treat bipolar disorder.

25. In July 1995, Parke-Davis's Marketing and Planning Department went beyond psychiatric conditions, and issued a Marketing Assessment on Neuropathic Pain and Spasticity. That report recommended that Parke-Davis pursue a similar publication strategy in the areas of neuropathic pain associated with peripheral nerve damage due to diabetes mellitus, trigeminal neuralgia, postherpetic pain, neuropathic facial pain, and reflex sympathetic dystrophy and disseminate the results of only "favorable" studies through publication in medical literature and key neurological and pain congresses. Parke-Davis approved these marketing assessments and adopted the recommendations regarding the publication strategy for the neuropathic pain market.

26. Parke-Davis's New Product Committee also approved the decision to conduct publication studies for Neurontin in migraine prophylaxis, and again restricted publication to only "positive" study results. As a result, the negative results of a clinical trial conducted in the 1980s relating to Neurontin and migraine have never been published.

27. Part of Defendants' strategy to increase sales of Neurontin was also to convince physicians to prescribe Neurontin at doses far exceeding the FDA-approved level. Defendants aggressively campaigned doctors to increase their doses of Neurontin despite the results of at least two clinical trials showing that increased doses did not achieve different results in patients.

28. Thus, by late 1995, senior management at Parke-Davis had committed the company to promoting Neurontin through a publication strategy for a myriad of off-label uses rather than by seeking FDA approval. The object of Defendants' publication strategy was to disseminate false and misleading information regarding these off-label uses for Neurontin as widely as possible through seminars, events, presentations and medical literature.

29. Scientific data and evidence did not exist supporting such off-label uses, and Defendants made, and caused others to make, misrepresentations and false statements as part of

their publication strategy in order to persuade doctors to prescribe Neurontin for off-label uses. No clinical trial showed that Neurontin was safe or effective for any of these conditions.

**D. The Promotion Enterprise**

30. In order to implement the publication strategy, Parke-Davis created the Promotion Enterprise composed of the Defendants, half a dozen medical marketing firms (the "vendor participants") and several dozen physicians (the "physician participants"). These participants acted together in promoting Neurontin to the healthcare industry. The acts of the Promotion Enterprise centered on the vendor participants organizing and hosting numerous seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of Neurontin (a/k/a peer-to-peer marketing events). The physician participants were not independent, but received "behind the scenes" coaching and remuneration from the vendor participants and Defendants.

31. The Promotion Enterprise also caused numerous articles and promotional pieces to be published in medical literature throughout the country misrepresenting the safety, efficacy, effectiveness and usefulness of Neurontin to treat a variety of off-label conditions. As part of the written publication component of the Promotion Enterprise, Defendants hired non-physician technical writers to write the necessary articles, with input and direction from Defendants and the vendor participants. Neither Defendants nor the vendor participants wanted their names on the articles so they paid physician participants for use of their names as the articles' "author." This practice is referred to as "ghostwriting." It gave the false impression that the article was unbiased and not sponsored by the drug manufacturer. In order to monitor the status of these publications, and in order to coordinate and execute the ghostwriting plan, marketing firms such as Medical Education Systems ("MES") and AMM/Adelphi were necessary. The role played by MES and

AMM/Adelphi in assisting the Defendants in creating publications was very similar to the role played by the marketing firms in the coordination of the peer-to-peer marketing events.

32. Because the Defendants' marketing personnel were not permitted to deliver the off-label message under FDA regulations, Defendants fraudulently circumvented this prohibition by training medical liaisons – technical employees of Defendants who were supposed to provide balanced scientific information to doctors – to market off-label and solicit interest in off-label uses. Defendants trained the medical liaisons to unlawfully engage in full scale promotion of Neurontin's off-label uses, with the use of non-scientific, anecdotal information designed to convince physicians to prescribe Neurontin for off-label conditions. The medical liaisons were trained to cold call physicians and sell them on the safety and medical efficacy and usefulness of Neurontin for off-label uses. Key aspects of this selling were misrepresentations. The first thing to be misrepresented was usually the status of the medical liaisons. With the full approval of Defendants' marketing officials, including John Ford, Phil Magistro and John Krukar, medical liaisons were routinely introduced as specialists in the specific drug they were presenting at a particular meeting. Thus, medical liaisons would be presented as experts in anti-epileptic drugs at one moment and an hour later be an expert in cardiac medication. Medical liaisons also were encouraged to represent themselves as medical researchers, even though they neither conducted medical research nor analyzed medical research performed by others. It was not uncommon for medical liaisons to be introduced as physicians, even though they had no such qualifications. Sales personnel were instructed to introduce medical liaisons as scientific employees who had been given temporary leave from their academic duties to make an individual presentation to the physician; the fact that the liaisons were part of Defendants' marketing program was intentionally hidden.

33. Medical liaisons were instructed in the clearest possible terms that they were to market and sell Neurontin for off-label uses. During a teleconference on May 24, 1996, John Ford, a senior marketing executive at Parke-Davis's Morris Plains headquarters, directly informed the medical liaisons that Neurontin had to be marketed for monotherapy, pain, bipolar disease, and other psychiatric uses, all of which were off-label uses. At another meeting with the medical liaisons, Ford was even blunter:

> I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable. . . . We all know Neurontin's not growing adjunctive therapy, besides that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing. . . . We can't wait for them to ask, we need to get out there and tell them up front. . . . That's where we need to be holding their hand and whispering in their ear Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything. . . . I don't want to see a single patient coming off Neurontin until they have been up to at least 4800mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug.

34. Defendants controlled the content of the messages being delivered at the seminars, meetings and other events and in the publications sponsored by the vendor and physician participants, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses. The physicians in the audience were deceived into thinking that the events were educational in nature and independent from control of the pharmaceutical manufacturer. Similarly, the physicians and other healthcare professionals who read the articles put together and published by the Promotion Enterprise were deceived into thinking these articles were unbiased and based on credible scientific data. And, the physicians who were contacted by Defendants' medical liaisons were deceived into thinking that these

employees were providing truthful balanced scientific information about Neurontin when in fact they were fraudulently acting as Defendants' surrogate sales force.

35. Defendants also paid "purported" grants to reward demonstrated Neurontin prescribers to continue to advocate the prescription of Neurontin for off-label uses to colleagues. Defendants' medical liaisons informed leading Neurontin prescribers that significant advocacy for Neurontin through "studies" would result in the payment of large grants. These studies did not involve significant work for the physicians. Oftentimes, the physicians contributed nothing at all to the study because Defendants frequently hired technical writers to write the articles for which the "authors" had been given grants. These grants were charged to Defendants' Neurontin marketing budget.

36. Defendants were aware that these articles and studies provided minimal scientific benefit. In a letter to the FDA in June 1997, Defendants submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" but failed to include any of the studies described below. Defendants intentionally neglected to report these studies to the FDA because Defendants knew the "research" had no scientific value and would not be deemed a scientific trial by the FDA. Payments Defendants made for these "studies" included, but were not limited to, the following:

| Funded Project | Payee | Payment |
|---|---|---|
| Statistical Analysis of Patients Treated With Neurontin For Pain | Hans Hansen, M.D. Statesville, NC | $7,000 |
| Reduction of Sympathetically Medicated Pain and Sudomotor Function | David R. Longmire, M.D. Russellville, AL | $7,000 |
| Data Entry for Neurontin and Pain Analysis | David Meyer, M.D. | [amount unknown] |

| Funded Project | Payee | Payment |
|---|---|---|
| Trial of Neurontin for Distal Symmetric Polyneuropathy Associated with AIDS | Joseph Weissman, M.D.<br>Atlanta, GA | $20,000 |
| Neurontin for Neuropathic Pain in Chronic Pain Syndromes | Lavern Brett, M.D.<br>Washington, DC | $25,000 |
| Retrospective Chart Analysis of Neurontin use with Bipolar Disorder Patients | Ralph S. Rybeck, M.D. | $5,000 |
| Retrospective Analysis of Neurontin in the Treatment of Pain | David R. Longmire, M.D.<br>Russellville, AL | $2,000 |
| Retrospective Analysis of Neurontin in the Treatment of Chronic Pain | Don Schanz, D.O.<br>Traverse City, MI | $8,000 |
| Case Histories Relating to Use of Neurontin as an Adjuvant Analgesic | Elizabeth J. Narcessian, M.D.<br>West Orange, NJ | $4,000 |

37. In order to hide the lack of scientific support for the off-label uses, and the Defendants' direct involvement in the seminars and articles, the Promotion Enterprise had no choice but to employ improper and unlawful sales and marketing practices. These practices included, *inter alia*: (a) deliberately misrepresenting the safety, medical efficacy, effectiveness and usefulness of Neurontin for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials; (c) deliberately concealing negative findings or the absence of positive findings; (d) misrepresenting the credentials and qualifications of certain of Defendants' employees as specialists, medical researchers, physicians and scientific employees in order to market and sell Neurontin; (e) wrongfully and illegally compensating physicians for prescribing Neurontin for various off-label uses; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data regarding Neurontin; (g) intentionally misrepresenting and concealing

Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Neurontin; (h) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the Enterprise; (i) fraudulently using medical liaisons to directly solicit, market and promote Neurontin for off-label uses to physicians; and (j) improperly financially inducing physicians to prescribe Neurontin by providing grants for their advocacy of Neurontin through "studies" which had minimal or no scientific value.

38. All of the participants in the Promotion Enterprise had the common purpose of aiding Defendants in deceptively and fraudulently marketing Neurontin for off-label uses and achieving significant "market expansion" for Neurontin. Each of the participants received substantial revenue from the scheme. The more successful these marketing events, the more events there would be in the future, and the more fees each of the participants would receive for organizing and participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist Defendants in their fraudulent promotion of Neurontin, notwithstanding that such a promotional campaign required the systematic repetition of false and misleading statements to thousands of physicians throughout the United States.

39. Parke-Davis, and subsequent to Pfizer's acquisition of Warner-Lambert, Pfizer, controlled and directed the overall Promotion Enterprise by (1) controlling the content of the presentations, speeches, promotional events and articles that misrepresented off-label usage of Neurontin, and (2) compensating the participants for their efforts on behalf of the Enterprise.

**1. The Role of Medical Marketing Firms – The Vendor Participants**

40. Third party medical marketing firms were critical to Parke-Davis's fraudulent marketing scheme. Indeed, the tactical plans Parke-Davis used to implement its fraudulent publication strategy were proposed by advertising companies such as Cline, Davis & Mann, Inc.

and Thompson Physicians World when representatives of those entities sat on Parke-Davis's Neurontin Extended Disease Team.

41. The tactical plans called for the medical marketing firms to organize and host, and the Defendants to review and pay for, hundreds of events, including medical education seminars, consultant meetings, advisory boards, speakers bureaus, teleconferences and dinner meetings where the physician participants of the Promotion Enterprise would deceptively promote the off-label use of Neurontin to thousands of doctors who were not prescribing Neurontin for adjunct epilepsy treatment. As detailed below, during each of these events, materially false and inaccurate information about Neurontin was given to the attendee physicians to induce them to prescribe Neurontin for off-label uses.

42. As part of the Promotion Enterprise, the third party marketing firms MES and AMM/Adelphi worked directly with Defendants and the physician participants to write and publish numerous articles discussing the use of Neurontin to treat various off-label conditions for which there was little or no credible scientific support.

43. The planning and coordination of these events and publications by the Promotion Enterprise required extensive use of the wires and mails, including mailing invitations to physicians, booking hotels and airplane tickets, arranging meals, scheduling teleconference calls, and coordinating the content of the presentations on Neurontin at the event and in the publications.

44. The firms who participated in the Promotion Enterprise included Cline, Davis & Mann, Inc. (and its Proworx division), Thompson Physicians World (and its Professional Postgraduate Services division), Sudler & Hennessey (and its Intramed division), MEDED, MES, Healthcare Communications Group and AMM/Adelphi. A brief description of the activities each

of these third party medical marketing companies took on behalf of the Promotion Enterprise that are known to the Plaintiffs follows, however, Plaintiffs' knowledge of these activities is very limited. Plaintiffs have only had the opportunity to review limited records, mostly of events between 1994 and 1998 that were held for the Northeast CBU. Yet Plaintiffs are aware that similar events were held across the country and that such events took place from 1994 through the present. Plaintiffs have not seen records of the vast majority of such events and cannot specify them because the records are in the possession, custody or control of Defendants or the other members of the Promotion Enterprise.

**a. Cline Davis**

45. Cline, Davis & Mann, Inc. ("Cline Davis") is a midtown Manhattan advertising and marketing firm, which does significant business with the pharmaceutical industry. Beginning in either late 1995 or early 1996, Cline Davis provided, and continues to provide, Defendants with strategic management services, including advising Defendants on strategies and tactics to expand the on-label and off-label use of Neurontin. To this day, Cline Davis directs the advertising campaigns for various Pfizer products, including Neurontin and Viagra. Through its Proworx division, Cline Davis also managed and coordinated various marketing events, including consultant meetings and other peer-to-peer sales marketing events for Neurontin.

46. Cline Davis shared with the Defendants the costs associated with the off-label marketing of Neurontin. For example, when Cline Davis exceeded the budgeted amounts under its strategic management services for Neurontin in 1996, Parke-Davis agreed to split the budget overrun with Cline Davis "in the spirit of partnership and a commitment to a long term relationship." The sharing of costs is evidence that the relationship between Cline Davis and the Defendants was that of partners in an enterprise, not principal and agent.

47. Cline Davis and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams. For example, at all relevant times hereto, a Cline Davis employee was a member of Parke-Davis's Extended Neurontin Disease Team, which was a high-level, confidential, internal interdisciplinary group composed of members from the following departments: Strategic Planning/Information Management, Neurontin Marketing, Advertising and Promotion, Product Planning, Medical Affairs, Forecasting, Training and Development, Healthcare Management, Public Relations, as well as representatives of Parke-Davis's five regional offices (known as "CBUs").

48. The Jupiter Beach, Florida consultants meeting held during the weekend of April 19-21, 1996 is one example of a meeting sponsored and produced by the Promotion Enterprise. Cline Davis's Proworx division worked with the Defendants and physician participants to put this meeting together for the purpose of encouraging neurologists from the Northeast CBU to increase their Neurontin prescriptions. Defendants' sales personnel were instructed by the Neurontin Marketing Team to select potential invitee neurologists from a list of the top prescription writers for antiepileptic drugs in the Northeast. During the meeting, attendees "were delivered a hard hitting message about Neurontin," and encouraged to prescribe Neurontin at higher doses for epilepsy. Technically the event was produced by Proworx, however, Defendants designed, monitored and approved all aspects of the presentation. Defendants selected the physician participant speakers, picked the presentation topics and previewed the content of the presentations to ensure they were acceptable. Defendants paid all expenses relating to the consultants meeting, including all payments for (i) the attending neurologists (valued at approximately $2,000 per attendee), (ii) the presentation expenses, (iii) all expenses and fees incurred by Proworx, and (iv) the substantial fees paid to the participant physicians.

49. Parke-Davis's control of the content of events produced by Cline Davis was further illustrated at a continuing medical education symposium coordinated by Cline Davis on behalf of the American Diabetes Association, held in Boston, Massachusetts, on June 23, 1997. At the eleventh hour, Cline Davis and Parke-Davis learned that one of the speakers, who was previously recommended by Parke-Davis, was going to describe negative results in her study of Neurontin's use for an off-label indication. Unable to cancel the presentation without grossly violating the rules for conducting accredited continuing medical education (CME) seminars, Cline Davis, in its own words, took steps "to counteract a possible 'negative' presentation." It planted a doctor in the audience to ask questions that would lead the presenter to make favorable statements during the question and answer period after her talk, and this plant "did indeed lead Dr. Bril to address some of the positive aspects of anticonvulsants and Neurontin." In a memorandum written by Cline Davis to Parke-Davis a day after the event, Cline Davis acknowledged its responsibility for allowing a presentation by a physician with an independent view, reaffirmed its "policy to complete a literature search to determine who authors favorable articles on the topics outlined" and assured Parke-Davis that "guidelines have been to set to ensure that this type of [negative presentation] situation does not happen again."

50. There existed between Cline Davis, the Defendants and the physician participants a common communication network for sharing information on a regular basis. Cline Davis and the Defendants routinely exchanged letters, memoranda, emails and phone calls, as did Cline Davis and the physician participants. There were also regular meetings among Cline Davis and Defendants, including high-level "face-to-face" meetings with the high-level marketing officials on both sides, where overall goals and strategies would be discussed. There were also more

frequent, lower-level "Toolbox" meetings, where individual strategies and tactics were discussed and progress in various areas of the off-label marketing scheme were monitored.

51. Some, but not all, of the events Cline Davis presented on behalf of the Promotion Enterprise included:

| **Event** | **Date** | **Location** |
|---|---|---|
| Neurontin Consultants Meeting | April 19-21, 1996 | Jupiter Beach, FL |
| Neurontin Consultants Meeting | May 3-4, 1996 | Philadelphia, PA |
| Neurontin Consultants Meeting | May 10-11,1996 | Boston, MA |

**b. Thompson Physicians World**

52. Thompson Physicians World ("Physicians World") is a New Jersey based marketing and medical education firm, which does considerable business with the pharmaceutical and healthcare industries. Physicians World managed and coordinated various marketing events, including speakers bureaus, advisory boards and other peer-to-peer marketing events.

53. Through its wholly owned and controlled Professional Postgraduate Services ("PPS") division, Physicians World also managed and coordinated various medical educational events. PPS purported to be a properly accredited sponsor of CME events.

54. Like Cline Davis, Physicians World began in 1995 to actively advise Parke-Davis on strategies and tactics to expand the on-label and off-label uses of Neurontin.

55. On December 22, 1995, at about the same time that Defendants formed their partnership with Cline Davis, Larry Perlow, Parke-Davis's Vice President of Portfolio Management, announced that Parke-Davis and Physicians World formed a "strategic partnership" to handle speakers bureaus, advisory boards and consultants meetings. The memorandum indicates that services formerly handled internally by Parke-Davis's Marketing Support Services would now by divided between Physicians World and Parke-Davis's Marketing Logistics

department. Under the strategic partnership, speakers bureaus, advisory boards and consultants meetings would be arranged by Physicians World; non-speaker medical education programs, grants and processing of all checks against advertising and promotion and departmental budgets would be handled by Marketing Logistics.

56. The same December 22, 1995 memorandum also announced that Parke-Davis and Physicians World would commingle employees. On January 1, 1996, Parke-Davis's Marketing Support staff joined Physicians World as full-time employees. Even though these employees were now based out of Physician World's Secaucus, New Jersey office, these employees continued to use the same toll free (800) numbers that they used at Parke-Davis, continued to use Parke-Davis letterhead, and provided the same services to Parke-Davis employees who contacted them.

57. In order to clarify marketing responsibilities in the wake of the strategic partnership and employee reassignments, Physicians World created various grids, which were circulated to marketing and sales colleagues in Parke-Davis and adopted as Parke-Davis policy. These grids explained the procedures for Parke-Davis and Physicians World to follow depending on whether the event fell under Physicians World's jurisdiction or remained under Marketing Logistics.

58. The use of these grids by both Parke-Davis and Physicians World, as well as the sharing of the toll free (800) numbers by the employees reassigned from Parke-Davis to Physicians World, and the continued use by the reassigned employees of Parke-Davis letterhead, evidences the continuing coordination and overlap of leadership functions, as well as the establishment of a joint communications network among Physicians World and Parke-Davis.

59. According to the written coordination policies jointly developed by Parke-Davis and Physicians World, if an event were non-promotional, *i.e.*, a CME, then the "accredited institution" -- not Parke-Davis or Physicians World -- was supposed to pick the speakers and the content of the presentations. The presentations were supposed to be fair and balanced, and were not supposed to pitch one drug product over another. According to the written policies, when the events were promotional, Parke-Davis and Physicians World were allowed to be "actively involved in speaker identification, recruitment as well as assistance with program content." However, the presentations of these handpicked speakers were supposed to be "strictly limited to approved indications," not off-label uses.

60. In practice, however, Physicians World and Parke-Davis actively, knowingly, and with full support of one another, circumvented or directly violated both of the above policies. In fact, the distinction between promotional and education events was rendered meaningless, as Physicians World owned and controlled PPS, which was the "accredited institution" for Physicians World's CME events. Regardless of the nature of the event, Physicians World, which was staffed by former Parke-Davis marketing employees and shared an address and an 800 telephone number with Parke-Davis, selected physician-speakers and attendees, and controlled the content of the presentations. Among the off-label programs Physicians World marketed where Parke-Davis controlled the content was an accredited home study program on pain which was planned to be circulated to 10,500 neurologists and pain doctors, and "educational" programs on Neurontin's use for psychiatric conditions. In both cases the accrediting institution, which was supposed to be independent, was Physicians World's subsidiary PPS.

61. Parke-Davis and Physicians World circumvented their promotional/educational polices in other ways. Parke-Davis occasionally held advisory committee meetings and

consultants meetings for the purpose of getting independent advice from experts regarding particular aspects of existing or planned drug products. When it came to Neurontin, however, Parke-Davis did not actually seek any input from the attendees and the real purpose of the meetings was to misrepresent to the attendees Neurontin's safety, medical efficacy, effectiveness and usefulness. The Neurontin meetings frequently were held at luxury resorts and the attendee's travel, room and board were paid by Parke-Davis.

62. There existed between Physicians World, the Defendants and the physician participants a common communication network for sharing information on a regular basis. Physicians World and the Defendants routinely exchanged letters, memoranda, emails and phone calls, as did Physicians World and the physician participants.

**c. Sudler & Hennessey**

63. Sudler & Hennessey is a midtown Manhattan advertising and marketing firm, which does significant business with the pharmaceutical and healthcare industries. Since 1995, Sudler & Hennessey provided and continues to provide the Defendants with strategic management services, advising them on strategies and tactics to expand the on-label and off-label use of Neurontin. Through its Intramed Educational Group division, Sudler & Hennessey also managed and coordinated various marketing events, including consultant meetings and other peer-to-peer marketing events.

64. Sudler & Hennessey and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams. Sudler & Hennessey also maintained systemic linkages with the physician participants, including continuing coordination of seminars, events and presentations.

65. Sudler & Hennessey recommended various unlawful ways for Parke-Davis to expand off-label uses for Neurontin. In fact, Sudler & Hennessey designed the blueprint for large

off-label marketing junkets. In July 1995, Sudler & Hennessey held a multi-day consultants meeting at the La Costa Resort and Spa in Carlsbad, California. This event featured lectures about off-label uses from physicians who became regular and willing participants in the Promotion Enterprise, including Drs. Schachter, Browne, Morrell, Morris, Pellock and Ritaccio. Collectively, these physicians have earned more than $500,000 (excluding travel, lodging and meals benefits) by participating in the Promotion Enterprise. The Carlsbad program even included a lecture that taught attendee physicians how to participate in the peer-to-peer marketing scheme as paid speakers and/or authors. This event served as the model for future large-scale marketing events.

66. Sudler & Hennessey also helped to organize the Neurobehavioral Working Group. The Group appeared to be a committee of concerned physicians from various medical fields who sought better pharmacological treatment for patients suffering from migraine, epilepsy, neuropathic pain, psychological disorders and sleep disturbances. In reality it was a marketing tactic created by Sudler & Hennessey and funded by Parke-Davis to create publications and deliver lectures that informed other physicians of Neurontin's supposed off-label efficacy in the major off-label categories by creating the belief that these categories are interrelated. There was no scientific evidence for this claim and no clinical evidence showing that Neurontin was effective for any of these conditions other than adjunctive epilepsy therapy. The physician lecturers for the Neurobehavioral Working Group were physician participants of the Promotion Enterprise including Drs. Devinsky, Morrell and Schachter (who collectively received more than $200,000 for their participation in the Enterprise).

67. Sudler & Hennessey has carried and continues to carry out many similar off-label marketing events all around the country. In those events, Sudler & Hennessey routinely recommends speakers who are favorable to Neurontin.

68. Some, but not all, of the events Sudler & Hennessey presented on behalf of the Off-Label Promotion Enterprise included:

| **Event** | **Date** | **Location** |
|---|---|---|
| Neurontin Consultants Meeting | April 19-21, 1996 | Jupiter Beach, FL |
| Neurontin Consultants Meeting | May 3-4, 1996 | Philadelphia, PA |
| Neurontin Consultants Meeting | May 10-11,1996 | Boston, MA |
| Emerging Concepts on the Use of Anticonvulsants CME at Marriott Sawgrass Resort | April 1997 | Ponte Vedra, FL |
| Emerging Concepts on the Use of Anticonvulsants CME | May 1997 | Saratoga Springs, NY |
| Emerging Concepts on the Use of Anticonvulsants CME | June 1997 | Boston, MA |
| Emerging Concepts on the Use of Anticonvulsants CME | July 1997 | Saratoga Springs, NY |
| Emerging Concepts on the Use of Anticonvulsants CME | May 1998 | Hershey, PA |
| Consultants Conference: Neuropathic Pain Syndrome | April 20, 1996 | Marco Island, FL |
| Current Applications in Neurological Conditions Grand Rounds at the Buckhead Resort | Sept. 27-28, 1997 | Atlanta, GA |
| Anticonvulsants, Current Applications in Neurological Conditions (“Weekend Pain Meeting”) at the Four Seasons Hotel | July 1998 | Boston, MA |
| Anticonvulsants, Current Applications in Neurological Conditions | July 1998 | New York, NY |
| Consultants Conference | Feb. 2-4, 1996 | Marco Island, FL |
| Mastering Epilepsy Regional Consultants Meeting at the La Costa Resort and Spa | July 1995 | Carlsbad, CA |
| New Treatment Options for the Management of Pain: The Role of Anticonvulsants at the Four Seasons | April 2000 | Irving, TX |
| Advisory Board at the Disney Yacht Club | May 26, 2000 | Orlando, FL |
| New Directions in the Understanding and Treatment of Pain at the Plaza Hotel | March 24, 2001 | New York, NY |
| New Directions in the Understanding and Treatment of Pain at the Hilton Novi | March 2–3, 2001 | Detroit, MI |

| Event | Date | Location |
|---|---|---|
| New Directions in the Understanding and Treatment of Pain at the Westin Galleria | May 4–5, 2001 | Houston, TX |
| New Directions in the Understanding and Treatment of Pain at the Harbor Court Hotel | February 9–10, 2001 | Baltimore, MD |
| New Directions in the Understanding and Treatment of Pain at the Fairmont Kansas City | March 9–10, 2001 | Kansas City, MO |
| New Directions in the Understanding and Treatment of Pain at the Peabody Memphis | May 11–12, 2001 | Memphis, TN |
| Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa | April 14-16, 2000 | Maui, HI |
| New Directions in the Understanding and Treatment of Pain at the Fairmont San Francisco | March 16–17, 2001 | San Francisco, CA |
| Advisory Board Meeting at the Westin Resort | June 16-18, 2000 | Hilton Head, SC |
| New Directions in the Understanding and Treatment of Pain at the Sheraton Universal City | May 18–19, 2001 | Universal City, CA |
| New Directions in the Understanding and Treatment of Pain at the Miami Biltmore | May 18–19, 2001 | Miami, FL |
| New Directions in the Understanding and Treatment of Pain at the Ritz Carlton New Orleans | March 23–24, 2001 | New Orleans, LA |
| New Directions in the Understanding and Treatment of Pain at the Sheraton Music City | March 23–24, 2001 | Nashville, TN |
| New Directions in the Understanding and Treatment of Pain at the Ritz Carlton St. Louis | March 30–31, 2001 | St. Louis, MO |

**d. MEDED/MEDCON**

69. Through at least 1997, Medical Education Programs, Ltd. ("MEDED") was a pharmaceutical marketing firm located in Danbury, Connecticut. Upon information and belief, MEDED was dissolved in 1997, and its principals established a spin-off pharmaceutical marketing firm known as Medical Education Consultants, LLC ("MEDCON"), located in Danbury, Connecticut. At all times relevant hereto, MEDED, and then subsequently MEDCON, provided and continues to provide the Defendants with strategic management services, advising them on strategies and tactics to expand the on-label and off-label use of Neurontin. MEDED/MEDCON

also managed and coordinated various marketing events, including regional consultant meetings for Defendants' various CBUs.

70. MEDED/MEDCON recommended various unlawful methods for the Defendants to expand off-label use and assisted in the implementation of those methods. For example, MEDED/MEDCON coordinated a series of Neuropathic Pain Consultants Meetings held at various regional resorts during the Spring of 1996 on behalf of the Southeast CBU. The speakers at these events were handpicked by Parke-Davis to present only certain information regarding Neurontin and encourage its use for conditions other than epilepsy. The number of attendees was far too large for a bona fide consultant meeting. MEDED/MEDCON also coordinated an Advisory Board on Neurontin and psychiatric uses for the Southeast CBU at the Grand Cypress Hotel in Orlando, Florida on May 2–4, 1997.

71. MEDED/MEDCON worked with Sudler & Hennessey and Defendants to provide services relating to the Neurobehavioral Work Group, including registering and organizing the Group's website.

72. MEDED/MEDCON also assisted the Defendants to create misleading articles about off-label Neurontin use pursuant to the publication strategy. Doctors Wilder, Schachter, Longmire, and Nicholson were retained as physician participants in the Promotion Enterprise and collectively received more than $400,000 for participating in the Enterprise. Upon information and belief, these physicians lent their names to articles they did not write regarding Neurontin's use in pain syndromes for inclusion in a supplement to the journal Pain Digest. The content of these articles was developed by MEDED. Although copies of the Neurontin pain supplement would be sent to the subscribers of Pain Digest, MEDED planned to distribute five times as many

copies to physicians who attended the off-label Neurontin events MEDED produced for Parke-Davis.

73. There existed between MEDED/MEDCON, the Defendants and the physician participants a common communication network for sharing information on a regular basis. MEDED/MEDCON and the Defendants routinely exchanged letters, memoranda, emails and phone calls, as did MEDED/MEDCON and the physician participants.

74. Some, but not all, of the events MEDED/MEDCON presented on behalf of the Promotion Enterprise included:

| **Event** | **Date** | **Location** |
|---|---|---|
| Consultants Conference: Neuropathic Pain Syndrome | April 20, 1996 | Marco Island, FL |
| Current Applications in Neurological Conditions Grand Rounds at the Buckhead Resort | Sept. 27-28, 1997 | Atlanta, GA |
| Anticonvulsants, Current Applications in Neurological Conditions ("Weekend Pain Meeting") at the Four Seasons Hotel | July 1998 | Boston, MA |
| Anticonvulsants, Current Applications in Neurological Conditions | July 1998 | New York, NY |

**e. MES**

75. Medical Educations Systems ("MES") is a marketing firm, which does significant business with the healthcare and pharmaceutical industries. MES specializes in coordinating CMEs, peer-to-peer sales events, and training pharmaceutical sales staffs. MES managed and coordinated various marketing events for the Defendants, including consultant meetings and other peer-to-peer marketing events concerning Neurontin.

76. MES and the Defendants maintained systematic linkages between themselves, including continuing coordination between their respective marketing teams. MES also

maintained systemic linkages with the physician participants, including continuing coordination of seminars, events, presentations and articles.

77. MES recommended various unlawful ways for Parke-Davis to expand off-label uses of Neurontin. For example, MES arranged what was purported to be a consultants meeting held in Chicago, Illinois on July 19-20, 1996. Although the topic was "Expanding the Paradigm of Antiepileptic Use," the meeting in reality was a marketing event meant to favorably misrepresent Neurontin for off-label uses, specifically pain and psychological uses. MES has carried and continues to carry out many similar off-label marketing events all around the country, all "in support of Neurontin." In those events, MES routinely selects speakers known to be acceptable to Defendants and who limit the data they provide to the audience to mislead the physicians as to the medical efficacy, effectiveness and usefulness of Neurontin.

78. MES also assisted the Defendants in publishing a variety of misleading articles about Neurontin and off-label uses. Defendants decided what topics the papers would cover and paid all expenses in connection with the creation of these publications. Technical writers for MES drafted the articles, and the articles were then submitted to a physician participant who "loaned" his or her name to the article in exchange for a payment of an honorarium. Working with MES, Defendants approved the topics of the articles, the content of the articles and, to the extent possible, the selection of the journal where the article was published.

79. Between 1997 and 1998, MES prepared at least twelve different articles in this manner. Although its proposal claimed to seek funding for articles relating to epilepsy, the actual articles that were developed were in fact mostly for off-label uses which included pain, behavioral disorders, mania and hypomania, mood and anxiety disorders, migraine, bipolar disorder, refractory epilepsy and monotherapy. The intended articles are as follows:

| Credited Author | Subject |
|---|---|
| M. Afzal Choudhry | Mental retardation (Epilepsia) |
| Ahmad Beydoun | Monotherapy (Neurology; Pharmacotherapy) |
| Mark H. Pollack | Mood and anxiety disorders (CNS Spectrums; Am J Psychiatry) |
| Patricia (Tricia) Suppes | Mania and hypomania (J Affective Disorders) |
| Basim Uthman | Monotherapy (JAMA) |
| Barry Gidal | Elderly patients (The Consultant Pharmacist) |
| Martha Morrell | Female patients (Am J Obstet Gynecol) |
| John M. Pellock | Mental retardation (Epilepsia) |
| John M. Pellock | Pediatric patients (Pediatrics) |
| Michael Merren | Pain and tremor (Journal of Southern Medicine) |
| Gail Anderson | Elderly patients (The Consultant Pharmacist) |
| Gail Anderson | Pharmacokinetics (Pharmacotherapy) |
| Maurice Druzin | Female patients (Am J Obstet Gynecol) |
| Hans Hansen | Chronic pain and migraine (Ann Intern Med) |

80. Defendants' role in creating, approving and sponsoring these articles was hidden from the public. For example, one of the MES articles, supposedly written by Dr. Pollack entitled *Gabapentin and Lamotrignine: Novel Treatments for Mood and Anxiety Disorders*, published in CNS Spectrums, noted that "an honorarium was received from Medical Education Systems for preparation of this article," but never revealed Parke-Davis's retention and payment of MES or the fact that MES personnel, while under contract to Parke-Davis, wrote the article.

81. There existed between MES, the Defendants and the physician participants a common communication network for sharing information on a regular basis. MES and the Defendants routinely exchanged letters, memoranda, emails and phone calls, as did MES and the physician participants.

### f. HCC

82. Healthcare Communications Group ("HCC") was a pharmaceutical marketing firm located in New Jersey. HCC managed and coordinated various marketing events for the Defendants, including consultant meetings and other peer-to-peer marketing events. HCC has carried and continues to carry out off-label marketing events for the Defendants all around the country. In those events, HCC selects speakers known to be acceptable to Defendants who support off-label use of Neurontin. Some, but not all, of the events HCC presented on behalf of the Promotion Enterprise included:

| Event | Date | Location |
|---|---|---|
| Emerging Concepts on the Use of Anticonvulsants CME at Marriott Sawgrass Resort | April 1997 | Ponte Vedra, FL |
| Emerging Concepts on the Use of Anticonvulsants CME | May 1997 | Saratoga Springs, NY |
| Emerging Concepts on the Use of Anticonvulsants CME | June 1997 | Boston, MA |
| Emerging Concepts on the Use of Anticonvulsants CME | July 1997 | Saratoga Springs, NY |
| Emerging Concepts on the Use of Anticonvulsants CME | May 1998 | Hershey, PA |

### g. AMM/Adelphi

83. AMM/Adelphi also assisted the Defendants in publishing a variety of articles about Neurontin and off-label uses. Similar to the tactics used with MES, Defendants decided what topics the articles would cover and paid all expenses in connection with the creation of these publications.

84. AMM/Adelphi developed the articles using its own technical writers, with very little, or in some cases, no input from the authors. This occurred even in connection with case histories that purported to describe the "author's" personal treatment of actual patients. The

"authors" that approved the final drafts were physician participants in the Promotion Enterprise and were paid an honorarium of $1,000 to lend their names to these articles.

85. AMM/Adelphi prepared at least eight different case history reports for the Northeast CBU alone in 1996. Most of the articles that were developed by AMM/Adelphi related to off-label uses of Neurontin, including pain, neuropathic pain, RSD and restless leg. The articles AMM/Adelphi was retained to prepare include, but are not limited to, the following:

| **Credited Author** | **Subject** |
|---|---|
| Smith | Neurontin for Treatment of Pain |
| Dwarkaneth | Neuropathic pain & RSD |
| Enrique Carrazana | Neuropathic pain (Journal of Pain and Symptom Management) |
| Steven Schachter | Neuropathic pain (Journal of Pain and Symptom Management) |
| Sutherland | Psychiatric uses |

86. There existed between AMM/Adelphi, the Defendants and the physician participants a common communication network for sharing information on a regular basis. AMM/Adelphi and the Defendants routinely exchanged letters, memoranda, emails and phone calls, as did AMM/Adelphi and the physician participants.

**2. The Role of Physicians – The Physician Participants**

87. One of Parke-Davis's principal strategies for fraudulently marketing Neurontin was to target key physicians, preferably within the major teaching hospitals, to serve as "Neurontin champions." These doctors promoted Neurontin to their peers through peer selling programs by (i) misrepresenting Neurontin's safety, medical efficacy, effectiveness and usefulness for off-label uses; (ii) claiming that Neurontin was being widely prescribed by other physicians for off-label uses without disclosing the deception that drove those prescriptions; (iii) suggesting possible mechanisms of action that could explain Neurontin's supposed efficacy in off-label areas, even

though they knew the mechanism of action was not and still is not understood; and (iv) misrepresenting that they were privy to the latest clinical data that would support off-label uses, but which had not yet been released.

88. To lure physicians to participate in the Promotion Enterprise, Defendants approached target doctors and informed them of Defendants' interest in funding research opportunities and clinical trials at their institutions; doctors who were willing to "speak favorably" about Neurontin could likely receive substantial funds in the form of research grants. Parke-Davis instructed its sales departments to select doctors at the major teaching hospitals to become "Neurontin experts," who in turn would be paid to deliver the Neurontin message to other physicians to increase Neurontin sales. This could be done formally to other physicians at marketing events or informally to colleagues within the hospital or practice.

89. Having recruited these physicians, the Promotion Enterprise created the false perception that physicians were clinically using Neurontin and investigating its efficacy for off-label uses on their own initiative, and not as a result of Defendants' illegal and fraudulent marketing activities. Defendants used a cadre of physicians (the physician participants) to create this perception. Defendants, principally through the vendor participants, paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to write journal articles and give talks at medical education seminars, advisory boards, consultant meetings, speakers bureaus and similar events that favorably discussed the off-label use of Neurontin. The individual physician participants received tens of thousands of dollars to promote Neurontin's off-label uses. In fact, some individual physician participants received more than $100,000 for their participation.

90. Among other activities, the physician participants gave off-label Neurontin presentations at national, regional and local marketing events set up by the Defendants and the vendor participants, and made favorable statements about Neurontin's off-label uses in teleconferences.

91. The physician participants were absolutely critical to the success of the Promotion Enterprise and all of the marketing plans crafted by the Defendants and the vendor participants. The participation of these select physicians allowed the Defendants and vendor participants to disguise promotional events as educational events or consultants meetings with purported neutral doctors, when in fact the speakers were biased and the events were promotional.

92. Some physicians participated in the Promotion Enterprise by publishing misleading journal articles and letters to the editor about off-label use of Neurontin. Defendants paid large sums of money, often in the form of research grants, to the physician participants in order to publish such articles. In some cases, the physician was not required to perform any research or even write the article. Marketing firms, including MES and AMM/Adelphi, who were financed by the Defendants, ghostwrote articles under the physician participants' names. Physicians merely had to "lend" their names to the articles, in exchange for a payment.

93. Physicians who participated in the Promotion Enterprise, either as speakers or as authors, entered into a mutually advantageous relationship with the Defendants. The more favorable a physician's statements were, the more he or she received in the form of speaker fees or research grants. Physicians who refused to deliver the favorable off-label message that the Defendants wanted were blackballed, and did not receive additional payments.

94. Physician participants worked with, and were retained by, multiple vendor participants. All of the physician participants had personal relationships with employees of the

Defendants, and it was frequently the Defendants who recommended to the vendors specific individual physician participants for events. Thus, a physician participant might speak at a resort for an educational event held by Sudler & Hennessey one weekend, give an almost identical presentation at a different resort hundreds of miles away for Physician World the next weekend, and provide the same information (and misrepresentations) at a dinner meeting sometime in between for MEDED at a third location.

95. Plaintiffs do not at this time know the identity of all of the physician participants. The Promotion Enterprise sponsored hundreds of events across the country and numerous articles between 1996 and 2004 and the plaintiffs have only had an opportunity to review the records of a small subgroup of these events and articles. Based on the records reviewed to date at least twenty-eight individual physician participants, identified below, received $25,000 or more each for participating in the Promotion Enterprise's activities for the time period indicated. Each of these physician participants appeared at multiple events and deceptively promoted off-label use of Neurontin at each event.

| **Physician Participant** | **Amount** | **Physician Participant** | **Amount** |
|---|---|---|---|
| Wilder, Joe (1/94-11/97) | $307,958 | Nitz, Dennis (5/95-5/96) | $58,187 |
| Ramsey, R. Eugene (2/94-12/97) | $163,446 | Yerby, Mark (3/94-12/97) | $57,741 |
| Browne, Thomas (9/93-12/97) | $142,364 | Wheless, James (1/95-11/97) | $54,829 |
| Ferrendelli, James (11/93-10/97) | $124,863 | Leppik, Ilo (12/93-11/97) | $49,250 |
| Beydoun, Ahmad (6/94-12/97) | $122,036 | Merren, Michael (3/94-11/97) | $47,606 |
| Pellock, John (3/94-10/97) | $119,940 | DeToledo, John (10/95-12/97) | $45,434 |
| Bergey, Gregory (9/93-12/97) | $106,987 | Ritaccio, Anthony (3/94-1/97) | $44,258 |
| Morrell, Martha (10/93-11/97) | $91,730 | Uthman, Basim (5/94-12/97) | $43,902 |
| McLean, Michael (7/93-11/97) | $83,343 | Smith, Michael (3/94-9/97) | $40,028 |
| Sachdeo, Rajesh (3/94-12/97) | $74,954 | Devinsky, Orrin (5/94-10/97) | $37,250 |

| Physician Participant | Amount | Physician Participant | Amount |
|---|---|---|---|
| Treiman, David (4/94-10/97) | $73,118 | Moshe, Solomon (4/94-12/97) | $34,250 |
| Morris, George (3/94-11/97) | $72,878 | Gelblum, Jefferey (1/96-12/97) | $28,978 |
| Schachter, Steven (5/94-9/97) | $71,477 | Longmire, David (11/95-5/97) | $28,469 |
| Bruni, Joseph (10/93-12/97) | $60,585 | Rosenfeld, William (3/94-2/97) | $26,730 |

**3. Participation and Knowledge of the Vendor and Physician Participants**

96. The vendor and physician participants were active participants in Defendants' publication strategy and were aware of Defendants' scheme to improperly market Neurontin for off-label uses. Cline Davis, Physicians World, Sudler & Hennessey, MEDED/MEDCON, MES and AMM/Adelphi each worked with the Defendants and the physician participants, for a common purpose, and as a continuing unit to perpetrate the fraudulent scheme relating to the creation of events, seminars, publications and articles promoting Neurontin for off-label uses for which it had not been proven to be safe and effective.

97. The vendor and physician participants' knowledge, involvement and activity is evidenced by:

- the coordination of the numerous events, seminars and presentations across the country among the Defendants, vendor participants and physician participants as to time, location and message content;
- the coordination of the numerous articles published as part of the Enterprise among the Defendants, vendor participants and physician participants as to time, publication and message content;
- the failure of each vendor and physician participant to advise government regulators, patients and private insurers, including Plaintiffs, of the existence and

spread of such misinformation concerning off-label uses of Neurontin;

- the acceptance by the vendor and physician participants of various types of incentives from Defendants in return for their agreement to host, coordinate and speak at events, and write, author, and have published articles containing misrepresentations, knowing that other physicians, consumers and healthcare professionals would use such information; and
- the agreement of the vendor and physician participants to permit Defendants to control the information relayed to the public in such presentations and articles.

98. Further, the vendor and physician participants knew that the programs they organized, hosted and participated in did not provide fair and balanced drug information to the attendee physicians. Among the information the Defendants, vendor participants and physician participants deliberately omitted from the events they were involved in was the following:

- the lack of clinical trial evidence to support Neurontin's off-label uses;
- negative clinical trial results demonstrating that Neurontin was no more effective than a placebo for several off-label conditions;
- negative anecdotal evidence that Neurontin did not work for off-label conditions;
- that virtually all publications and studies that allegedly supported Neurontin's off-label use had been funded by Defendants;
- that virtually all publications and studies that allegedly supported Neurontin's off-label use had been initiated by Defendants pursuant to a corporate marketing plan designed to increase off-label sales;
- that no scientific evidence explained Neurontin's mechanism of action, which in turn meant there was no scientific explanation regarding why Neurontin might

work for the off-label uses for which it was being promoted;

- that Parke-Davis had deliberately decided not to publish or publicize any studies concluding that Neurontin was not effective for off-label uses;
- that the participating doctors who were conducting the peer selling had been paid substantial money to use Neurontin on their patients for off-label purposes;
- that the events the physicians were attending were neither fair nor balanced and were created to ensure the physicians would not hear a fair and balanced examination of Neurontin for off-label uses; and
- that the events were not funded, as advertised, by an unrestricted grant from the Defendants, but that the grants were conditioned upon the participating vendors and sponsoring institutions putting on presentations that painted off-label use of Neurontin in the most favorable light.

## E. Defendants' Use of the Promotion Enterprise to Fraudulently Promote Neurontin – The Misrepresentations

### 1. Introduction

99. In the context of describing properties of approved prescriptions drugs, the terms "effective" and "efficacy" have specific and well-understood meanings. Because the FDA will only find a pharmaceutical to be effective if the proposed use is supported by substantial evidence consisting of well designed, well controlled clinical trials that establish a causal relationship to a statistically significant degree, 21 U.S.C. § 355(d), a statement that a drug is "effective," or "works," or "has been proven to" is understood to mean that well controlled clinical studies support the use. To make such a statement without clinical trial proof is misleading. Further, the failure to inform physicians that no well-controlled clinical trials supports a representation of a drug's efficacy is a failure to disclose a material fact which companies marketing pharmaceuticals

in the United States are obligated to disclose. Where such information is not provided, any statements about Neurontin's effectiveness for off-label use is false, misleading, distorted, inaccurate, not fair and balanced and omits material facts that must be disclosed.

100. Although Defendants have extensively promoted Neurontin for off-label purposes, few placebo-controlled, clinical studies have been conducted on off-label uses of Neurontin. Most of those that have been conducted produced negative or inconclusive results. Placebo-controlled clinical trials for Neurontin's use for bipolar disorder, unipolar disorder, essential tremor, spasticity, controlled diabetic pain and panic disorder all failed to show that Neurontin is effective for those conditions.

101. Although Plaintiffs are aware of Defendants' policy of suppressing unfavorable studies because of the express terms of the corporate decisions implementing the publication strategy, all information regarding negative studies funded by Parke-Davis remains in the sole possession, custody or control of Parke-Davis and/or members of the Promotion Enterprise. Defendants have never produced the results of these studies to the public or to the Plaintiffs and their attorneys.

**2. False and Misleading Statements Regarding Pain**

102. At each of the pain presentations known to the Plaintiffs, presenters expressly stated, or implied, that Neurontin was medically safe, efficacious, effective and useful for the treatment of pain. A representative statement was made by Dr. David Longmire at the Jupiter Beach consultants meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 consultants meeting at the Ritz Carlton in Boston, and another physician participant, Dr. Steven Schacter made a similar statement at the same meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Plaintiffs are aware of comparable statements being made by another

physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach consultants meeting in May 1996 at the Boston Ritz Carlton consultants meeting, and in June 1996 at a Philadelphia consultants meeting. Upon information and belief, similar statements were made at all events presented by the Promotion Enterprise that discussed Neurontin's use for pain, which included, but are not limited to, the following events

| **Event** | **Date** | **Location** |
|---|---|---|
| Neurontin Consultants Meeting | April 19-21, 1996 | Jupiter Beach, FL |
| Neurontin Consultants Meeting | May 3-4, 1996 | Philadelphia, PA |
| Neurontin Consultants Meeting | May 10-11,1996 | Boston, MA |
| Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa | April 14-16, 2000 | Maui, HI |
| Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort | April 28-30, 2000 | Sedona, AZ |
| New Treatment Options for the Management of Pain: The Role of Anticonvulsants at the Four Seasons | April 2000 | Irving, TX |
| Advisory Board at the Disney Yacht Club | May 26, 2000 | Orlando, FL |
| New Directions in the Understanding and Treatment of Pain at the Plaza Hotel | March 24, 2001 | New York, NY |
| New Directions in the Understanding and Treatment of Pain at the Hilton Novi | March 2-3, 2001 | Detroit, MI |
| New Directions in the Understanding and Treatment of Pain at the Westin Galleria | May 4-5, 2001 | Houston, TX |
| New Directions in the Understanding and Treatment of Pain at the Harbor Court Hotel | February 9-10, 2001 | Baltimore, MD |
| New Directions in the Understanding and Treatment of Pain at the Fairmont Kansas City | March 9-10, 2001 | Kansas City, MO |
| New Directions in the Understanding and Treatment of Pain at the Peabody Memphis | May 11-12, 2001 | Memphis, TN |
| Advisory Board Meeting at the Grand Wailea Resort Hotel and Spa | April 14-16, 2000 | Maui, HI |
| New Directions in the Understanding and Treatment of Pain at the Fairmont San Francisco | March 16-17, 2001 | San Francisco, CA |
| Advisory Board Meeting at the Westin Resort | June 16-18, 2000 | Hilton Head, SC |
| New Directions in the Understanding and Treatment of Pain at the Sheraton Universal City | May 18-19, 2001 | Universal City, CA |

| Event | Date | Location |
|---|---|---|
| New Directions in the Understanding and Treatment of Pain at the Miami Biltmore | May 18-19, 2001 | Miami, FL |
| New Directions in the Understanding and Treatment of Pain at the Ritz Carlton New Orleans | March 23-24, 2001 | New Orleans, LA |
| New Directions in the Understanding and Treatment of Pain at the Sheraton Music City | March 23-24, 2001 | Nashville, TN |
| New Directions in the Understanding and Treatment of Pain at the Ritz Carlton St. Louis | March 30-31, 2001 | St. Louis, MO |
| New Advances in the Treatment of Neuropathic Pain | October 9-11, 1998 | Madeira, Portugal |

103. The speakers who made these statements did not have any clinical evidence to support such claims. The statements implied that clinical trial evidence sufficient to establish medical safety and efficacy, effectiveness and usefulness existed, but with the exception of Neurontin's use for postherpetic neuralgia, there is no clinical trial evidence that supports any claim that Neurontin is effective for the treatment of pain.

104. In virtually all of the presentations in which Neurontin's use for pain was promoted, neither the physician participant nor any person connected to the Promotion Enterprise acknowledged that no clinical trial evidence supported a claim of efficacy. Defendants' failure to disclose this material information made any statement that Neurontin was effective for any pain syndrome, other than postherpetic neuralgia, false and misleading.

105. At every presentation concerning Neurontin's use for pain, "favorable" anecdotal evidence was presented to support Neurontin's use. But, unfavorable anecdotal evidence was not disclosed even though Defendants were aware of such evidence. Defendants' failure to provide a fair and balanced presentation of the anecdotal information made their presentation false and misleading.

106. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's safety and medical efficacy, effectiveness and usefulness in treating pain. The following are representative false statements by Defendants' sales force to doctors. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports which exist for the last several years. Upon information and belief, review of more recent verbatim reports will demonstrate that similar statements were regularly made by the Defendants' sales forces from 1998 through 2004.

- In October 1995, a Parke-Davis sales representative stated that Neurontin had received a "New indication for chronic pain."
- In December 1995 a Parke-Davis sales representative stated that Neurontin was a "Good anticonvulsant for chronic pain and restless leg syndrome."
- In July 1996, a Parke-Davis sales representative stated that Neurontin was "Effective for many types of chronic pain."
- In December 1996, a Parke-Davis sales representative stated that Neurontin was "Good for back pain; neuropathic pains."

### 3. False and Misleading Statements Regarding Diabetic Peripheral Neuropathy

107. Prior to October 16, 1997, Parke-Davis had no reasonable basis to claim or suggest that Neurontin was safe or effective or could be possibly effective to treat diabetic peripheral neuropathy. Nonetheless, at events produced by the Promotion Enterprise, physician participants routinely falsely stated that Neurontin was safe and effective for this condition. For example, at the Jupiter Beach consultants meeting in April 1996, Dr. Nicholson stated that diabetic neuropathy patients "will" have their burning sensations relieved with the use of Neurontin. No clinical trial

support or comparable evidence existed when this statement was made. Upon information and belief, similar statements were made at all events presented by the Promotion Enterprise that discussed Neurontin's use as a treatment for diabetic peripheral neuropathy, which include, but are not limited to, the following events:

| Event | Date | Location |
|---|---|---|
| Neurontin Consultants Meeting | April 19-21, 1996 | Jupiter Beach, FL |
| New Advances in the Treatment of Neuropathic Pain | October 9-11, 1998 | Madeira, Portugal |

108. In 1996, Parke-Davis funded a placebo-controlled clinical trial concerning the use of Neurontin to treat diabetic peripheral neuropathy. The trial was conducted by Dr. Kenneth Gorson, a doctor at St. Elizabeth's Hospital in Boston, Massachusetts. The results of Gorson's study were negative. On August 23, 1997, Gorson submitted a draft of his study to Parke-Davis, accompanied by an abstract plainly stating that the study did not support Neurontin's use for diabetic peripheral neuropathy. Its conclusion stated that gabapentin "is probably no more effective than a placebo in the treatment of painful diabetic neuropathy."

109. Nonetheless, Parke-Davis wrote and circulated a revised abstract that hid and misrepresented Dr. Gorson's negative findings and gave his study a more favorable conclusion. In January 1998, Parke-Davis circulated this revised abstract of the Gorson article with a conclusion stating, "Gabapentin may be effective in the treatment of painful diabetic neuropathy. Our results suggest that further studies evaluating higher dosages of gabapentin are warranted." Dr. Gorson refused to adopt this revision. In February 1999, more than one year later and almost two years after the study's completion, the results of Dr. Gorson's study were published in a letter to the editor of the Journal of Neurology, Neurosurgery & Psychiatry, vol. 66, pages 251-52. The

article concluded, "The results of this study suggest that gabapentin is probably ineffective or only minimally effective for the treatment of painful diabetic neuropathy at a dosage of 900 mg/day."

110. Parke-Davis also submitted to the Drugdex Drug Information System, a widely used computer database that contains pharmaceutical information and article citations, a draft of an article which contained language that is consistent with the false abstract of Dr. Gorson's study circulated by Parke-Davis but which is not contained in the actual article. Drugdex published a citation to the Gorson article, which states, falsely, "the authors suggest that higher doses of gabapentin are needed." No such language is in the article. The Drugdex article omits the author's conclusion that gabapentin is "probably ineffective" for the treatment of painful diabetic neuropathy.

111. After it received the results of the Gorson study, the Promotion Enterprise continued to promote Neurontin as effective for treating diabetic peripheral neuropathy at hundreds of presentations nationwide. The physician participants did not describe the results and conclusions of Dr. Gorson's study, nor did Defendants' representatives provide such information. Defendants' failure to describe the negative studies breached their obligation to provide fair and balanced information and made their representations regarding Neurontin's use for diabetic peripheral neuropathy false and misleading.

#### 4. False and Misleading Statements Regarding Restless Leg Syndrome (RLS)

112. At events produced by the Promotion Enterprise, physician participants routinely misrepresented that Neurontin was effective for the treatment of restless leg syndrome. Events presented by the Promotion Enterprise that discussed Neurontin's use as a treatment for restless leg syndrome or RSD, included, but are not limited to, the Advisory Board Meeting held at the Hyatt Regency Hotel on March 29, 2000 in San Antonio, Texas.

113. Upon information and belief, at every presentation concerning Neurontin's use for restless leg syndrome, neither the physician participants, the vendor participants, nor the Defendants informed the attendee physicians that Defendants had deliberately suppressed negative studies pursuant to the publication strategy. As described below, there was in fact at least one negative study that found that Neurontin was not effective for this condition, and upon information and belief, the results of this study were never disclosed when Neurontin's use for restless leg syndrome was discussed.

114. Pursuant to its plan to reward doctors who used Neurontin for off-label indications, in 1996 Parke-Davis funded an open label study conducted by Dr. Bruce Ehrenberg of the New England Medical Center on whether Neurontin was effective for periodic limb movement, a sleep disorder closely related to restless leg syndrome.

115. Dr. Ehrenberg's study was negative, finding that sleep improved for less than half of the participants who took the drug. Moreover, the drug did not affect any of the participants' limb movements during sleep.

116. Despite this study, Parke-Davis's medical liaisons falsely told physicians that Dr. Ehrenberg's patients had a 90% response rate to Neurontin. Medical liaisons discussed making such assertions routinely in a June 1996 conference call taped by Dr. David Franklin. Neither the medical liaisons nor the physician participants amended their statements to physicians once the results of Dr. Ehrinberg's study were known.

117. Former Parke-Davis officials have admitted that although the results were not favorable, the results of Dr. Ehrenberg's study should have been published and made known to doctors. Indeed, Parke-Davis hired AMM/Adelphi to organize his data and to develop a manuscript for him. After the negative results were received, however, Parke-Davis took no steps

to publish an article based on Dr. Ehrenberg's results. Parke-Davis's actions were consistent with its publication strategy, which intended to only publish studies with favorable results. Parke-Davis's policy of only publishing and disclosing the results of favorable studies directly violated its obligation to disclose favorable and unfavorable results pursuant to its obligation to make only fair and balanced statements relating to its drug products.

118. In addition, an article widely circulated by Defendants concerning the use of Neurontin in the treatment of Restless Leg Syndrome asserted that the authors Gary A. Mellick and Larry B. Mellick had not and never would receive financial benefit from anyone with an interest in Neurontin. The Mellick brothers had in fact received tens of thousands of dollars for acting as speakers at Defendants' events. Moreover, Gary Mellick never disclosed that he was a consultant for Parke-Davis and was assisting the company in developing the market for off-label uses of Neurontin.

119. Although they were not supposed to discuss off-label indications with physicians, Parke-Davis sales representatives regularly made false statements to doctors about Neurontin's safety, efficacy, effectiveness and usefulness in treating restless leg syndrome. The following are representative false statements by the sales force to doctors. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statements were regularly made by the Defendants' sales forces from 1998 through 2004.

- In August 1996, a Parke-Davis sales representative falsely stated that Neurontin was "Effective in controlling postherpetic pain; restless leg syndrome, peripheral neuropathy, migraine headache."

- In December 1996, a Parke-Davis sales representative stated that Neurontin was "Good for restless leg syndrome."

**5. False and Misleading Statements Regarding Bipolar Disorder**

120. When Parke-Davis created its original marketing assessment for the use of Neurontin to treat bipolar disorder in May 1995, it knew that there was no scientific rationale for Neurontin being a safe and effective agent to treat bipolar disorder, which is commonly called manic depression. Nonetheless, Parke-Davis planned and intended the Promotion Enterprise to promote Neurontin heavily for bipolar disorder. Events presented by the Promotion Enterprise that discussed Neurontin's use as a treatment for bipolar disorder included, but are not limited to, the following:

| Event | Date | Location |
|---|---|---|
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |
| Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess | January 21-23, 2000 | Scottsdale, AZ |
| Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire | March 24-26, 2000 | Beverly Hills, CA |
| Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place | April 7-9, 2000 | New Orleans, LA |
| Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort | April 28-30, 2000 | Sedona, AZ |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert | March 16, 1998 | Boston, MA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset Grill | March 16, 1998 | Nashville, TN |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe | March 16, 1998 | Seattle, WA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at | March 17, 1998 | St. Pete's Beach, FL |

| Event | Date | Location |
|---|---|---|
| Patrick's Bayside Bistro | | |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel | March 17, 1998 | Portland, OR |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club | March 18, 1998 | Philadelphia, PA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead | March 18, 1998 | Atlanta, GA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel | March 18, 1998 | San Francisco, CA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant | March 19, 1998 | Baltimore, MD |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia | March 19, 1998 | New York, NY |
| The Use of Anticonvulsants in Psychiatry | October 23–25, 1998 | Barcelona, Spain |

121. On every occasion the Promotion Enterprise claimed that Neurontin was effective for the treatment of bipolar disorder, it was making false statements to physicians with the intent of having physicians prescribe Neurontin to treat this condition. Every occasion the Promotion Enterprise gave a presentation on bipolar disorder without informing physicians that there was no scientific basis supporting this use, it failed to inform the physicians of material information, and its statements were false and misleading.

122. As early as May 20, 1997, Parke-Davis knew that clinical trial evidence established that Neurontin was not significantly superior to a placebo in treating bipolar disorder. At the 1997 annual meeting of the American Psychiatric Association in San Diego, California, investigators presented the results of a placebo-controlled clinical trial comparing a placebo, lamotrigine and Neurontin on depression and bipolar patients. The results showed that Neurontin was not significantly more effective than a placebo and considerably less effective than the competitor

drug lamotrigine. Thus, by the third quarter of 1997, Parke-Davis knew that the results of its own clinical trial of Neurontin showed that a placebo was more effective than Neurontin in treating bipolar disorder.

123. Despite the results of the clinical trials, the Promotion Enterprise continued to make presentations to physicians promoting Neurontin to treat patients with bipolar disorder. For example, the Promotion Enterprise created and sponsored a series of dinner meetings for psychiatrists entitled "Closing the Psychiatry-Neurology Divide: Emerging Uses of Anticonvulsants." This program was presented dozens of times in 1998, including in St. Petersburg, Florida at Patrick's Bayside Inn. As part of the program, psychiatrists were informed that Neurontin was indicated for bipolar disorder, that early evidence suggested that it had anti-depressive and mood stabilizing effects, and that "data are increasing but currently limited to favorable case reports and open trials." The program did not inform attendees of the unfavorable clinical trials that found that Neurontin was not effective for bipolar disorder.

124. Similarly, Parke Davis's sales force regularly made false statements to physicians about Neurontin's utility in treating bipolar disorder. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statements were regularly made by the Defendants' sales forces from 1998 through 2004. Representative statements made to physicians include:

- At a Parke-Davis marketing event in 1997, Parke-Davis falsely stated that Neurontin was "effective" for "bipolar."
- In December 1998, a Parke-Davis sales representative falsely stated to a physician that Neurontin was an "effective treatment of bipolar disorder."

- At a Parke-Davis marketing event in December 1998, Parke-Davis falsely stated that Neurontin was "Effective on bipolar."
- At a Parke-Davis marketing event at the airport Marriott in San Francisco in August 1998, Parke-Davis falsely stated that Neurontin was "Innovative and effective … for bipolar II."

125. Parke-Davis did not publish the results of the negative bipolar disorder clinical trial until 2000. Drugdex has never included citations to either of the articles that document the negative clinical trials for bipolar disorder in its compendium.

**6. False and Misleading Statements Regarding Social Phobia**

126. At events produced by the Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by the Promotion Enterprise which discussed Neurontin's use as a treatment for bipolar disorder included, but are not limited to, the following:

| **Event** | **Date** | **Location** |
|---|---|---|
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |
| Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess | January 21-23, 2000 | Scottsdale, AZ |
| Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire | March 24-26, 2000 | Beverly Hills, CA |
| Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place | April 7-9, 2000 | New Orleans, LA |
| Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort | April 28-30, 2000 | Sedona, AZ |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert | March 16, 1998 | Boston, MA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset | March 16, 1998 | Nashville, TN |

| Event | Date | Location |
|---|---|---|
| Grill | | |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe | March 16, 1998 | Seattle, WA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Patrick's Bayside Bistro | March 17, 1998 | St. Pete's Beach, FL |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel | March 17, 1998 | Portland, OR |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club | March 18, 1998 | Philadelphia, PA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead | March 18, 1998 | Atlanta, GA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel | March 18, 1998 | San Francisco, CA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant | March 19, 1998 | Baltimore, MD |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia | March 19, 1998 | New York, NY |
| The Use of Anticonvulsants in Psychiatry | October 23–25, 1998 | Barcelona, Spain |

Upon information and belief, at each of these events, participating physicians expressly stated, or implied, that Neurontin was effective for the treatment of social phobia.

127. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, the only clinical study conducted was inconclusive regarding Neurontin's effectiveness for the treatment of social phobia. Prior to its receipt of results of its social phobia clinical trial on July 22, 1997, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating social phobia, because no clinical trial data existed.

128. Even after Parke-Davis received the results from its clinical study in July 1997, it could not state that the evidence unconditionally supported Neurontin's use for social phobia. The authors of the study admitted that the data was limited. They did not conclude that Neurontin was effective, and acknowledged that further studies were necessary to determine whether a dose-response relationship existed. The authors of the study could not explain why there appeared to be wide ranges of effectiveness between male subjects and female subjects, and between individuals above age thirty-five compared to those below age thirty-five.

129. Notwithstanding the lack of clinical trial evidence to support Neurontin's use for patients with social phobia, the Promotion Enterprise held numerous events where the physician participants informed physicians that Neurontin was effective for the treatment of social phobia, and failed to inform attendees of the limitations of the clinical trial evidence. Such statements were false and misleading.

**7. False and Misleading Statements Regarding Panic Disorder**

130. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless at events produced by the Promotion Enterprise, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by the Promotion Enterprise which discussed Neurontin's use as a treatment for panic disorder included, but are not limited to, the following:

| **Event** | **Date** | **Location** |
|---|---|---|
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |
| Parke-Davis Speakers Bureau Meeting at the Fairmont Scottsdale Princess | January 21-23, 2000 | Scottsdale, AZ |
| Merritt-Putnam Speakers Bureau | March 24-26, | Beverly Hills, CA |

| Event | Date | Location |
|---|---|---|
| Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire | 2000 | |
| Merritt-Putnam Speakers Bureau at the Wyndham New Orleans at Canal Place | April 7-9, 2000 | New Orleans, LA |
| Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders at the Enchantment Resort | April 28-30, 2000 | Sedona, AZ |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Maison Robert | March 16, 1998 | Boston, MA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Sunset Grill | March 16, 1998 | Nashville, TN |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Pescatore Fish Cafe | March 16, 1998 | Seattle, WA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Patrick's Bayside Bistro | March 17, 1998 | St. Pete's Beach, FL |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Heathman Hotel | March 17, 1998 | Portland, OR |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Downtown Club | March 18, 1998 | Philadelphia, PA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Morton's of Chicago – Buckhead | March 18, 1998 | Atlanta, GA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Huntington Hotel | March 18, 1998 | San Francisco, CA |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at the Brass Elephant | March 19, 1998 | Baltimore, MD |
| 1998 CME Psychiatry Dinner Meeting and Teleconference Series: Dinner Meeting at Ristorante DeGrezia | March 19, 1998 | New York, NY |
| The Use of Anticonvulsants in Psychiatry | October 23–25, 1998 | Barcelona, Spain |

131. The speakers who made these statements did not have any clinical evidence to support such claims. These statements implied that clinical trial evidence sufficient to establish causation existed, but as discussed below, clinical studies that were conducted did not find that Neurontin is effective for the treatment of panic disorder. On every occasion the Promotion Enterprise gave a presentation on the use of Neurontin for bipolar disorder without informing physicians that there was no scientific basis for using Neurontin, it omitted to inform the physician attendees of material information that was required to be presented in order for its statements on the use of Neurontin to not be misleading and false and to satisfy its obligation to provide fair and balanced information.

132. Not until October 1997, did Parke-Davis receive results of its own clinical trial which found that Neurontin was no more efficacious than a placebo in treating panic disorder. Parke-Davis did not publish the negative results of this clinical trial until 2000. Despite the results of the clinical trial, the Promotion Enterprise continued to mislead physician attendees at various events and seminars sponsored by the Promotion Enterprise by failing to disclose the negative clinical trial evidence and representing that Neurontin was effective and useful to treat panic disorder.

**8. False and Misleading Statements Regarding Migraine**

133. Parke-Davis knew that there was no preclinical rationale supporting the use of Neurontin in migraine prophylaxis.

134. Parke-Davis conducted a twelve-week migraine prophylaxis study in Europe during the late 1980s which revealed no statistically significant difference in migraine attack frequency between placebo and 900 milligrams of Neurontin therapy.

135. In addition to the failed European migraine trial, Parke-Davis knew of several reports of negative results of Neurontin for migraine use, including reports from Dr. Seymour

Solomon, Director of the Headache Unit at Montefiore Medical Center; Dr. John Rothrock, Chairman of the Department of Neurology at University of Alabama; Dr. Kenneth Michael Anthony Welch, Professor of Clinical Neurology at the University of Michigan; and Dr. Fred Michael Cutrer, Department of Neurology at Massachusetts General Hospital.

136. Parke-Davis never disclosed the negative European trial on migraine to any persons outside of the company, and the negative results were never published.

137. On May 25, 1996, Parke-Davis held an advisory board meeting to discuss "Gabapentin in the Management of Migraine." Parke-Davis's principal investigator for Neurontin and migraine chaired the meeting, and there were several other physicians in attendance. There were also several Parke-Davis employees in attendance, including the author of the marketing assessment, John Boris, who was aware of the failed European clinical trial. Vendor participant AMM/Adelphi ran the meeting. The purpose of the meeting was to discuss Neurontin's possible utility in the area of migraine and to solicit feedback on the development of clinical trials.

138. At the advisory board meeting, Parke-Davis suppressed any reference to the failed migraine study of the late 1980s. Leslie Magnus-Miller, Parke-Davis's Medical Affairs Director, was directly asked, "But do you have any data [relating to Neurontin and migraine]?" Dr. Magnus-Miller responded: "We didn't…No, not really, because we didn't capture headache baseline." Edda Guerrero added: "Unfortunately we did not, not even in monotherapy I think. Right?" John Boris did not correct this misstatement. Parke-Davis also failed to mention that there was "no established preclinical rationale that would support the use of Neurontin in migraine prophylaxis."

139. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and the Promotion Enterprise, the Promotion Enterprise regularly presented programs in which

physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but were not limit to, the following:

| Event | Date | Location |
|---|---|---|
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |
| Gabapentin in the Management of Migraine | May 25, 1996 | Short Hills, NY |

Such statements were false and misleading. In these presentations, Parke-Davis failed to inform physician participants of the failed migraine trial or the negative anecdotal evidence it received from its own advisory board physicians. It also failed to inform physicians that there was no established rationale or clinical trial evidence that would support the use of Neurontin for migraine. Defendants' failure to provide this information made any prior statements about Neurontin's use for migraine false and misleading.

140. Parke-Davis sales representatives routinely made false statements regarding the safety, efficacy, effectiveness and usefulness of Neurontin in treating migraine. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statement were regularly made by the Defendants' sales forces from 1998 through 2004. Representative statements made to physicians include a statement made by a Parke-Davis salesperson in August 1996 who stated "Effective in controlling … migraine headache."

**9. False and Misleading Statements Regarding Other Indications**

141. Neurontin was prescribed for hundreds of additional off-label indications for which there is no scientific support as to its safety, efficacy, effectiveness or usefulness. Pursuant to marketing strategies and tactics developed by Parke-Davis and the Promotion Enterprise, the

Promotion Enterprise regularly presented programs in which physician participants misrepresented Neurontin as being effective for conditions other than those described above. Such statements were false and misleading because there was no clinical trial evidence showing that Neurontin was safe and effective for the treatment of any conditions other than adjunct therapy for partial seizures and postherpetic neuralgia. In these presentations, Parke-Davis failed to inform physician attendees that there was no established rationale that would support the use of Neurontin for conditions other than adjunct therapy for partial seizures and postherpetic neuralgia. Defendants' failure to provide this information rendered any prior statements about Neurontin's use for conditions other than adjunct therapy for partial seizures and postherpetic neuralgia false and misleading.

### 10. False and Misleading Statements Regarding Monotherapy for Epilepsy

142. The Promotion Enterprise repeatedly fraudulently asserted that Neurontin was effective as a monotherapy treatment for epilepsy. Parke-Davis knew that proof of efficacy for monotherapy required successful completion of two clinical trials demonstrating Neurontin's efficacy. Clinical Study 945-82, a double-blind, placebo-controlled study, was designed to be a pivotal study in support of monotherapy. But the results were negative, failing to demonstrate that Neurontin was effective in treating seizures at doses up to 2400 milligrams per day. In addition to failing to establish monotherapy efficacy, clinical trial 945-82 failed to establish a dose-response at 600, 1200 and 2400 milligrams per day. Thus, as early as November 1995, Parke-Davis knew that clinical trial 945-82 did not support a monotherapy indication.

143. Parke-Davis also knew that another clinical trial concerning Neurontin's use as a monotherapy, the Eastern European pilot study 945-177, an extension of the 945-77 protocol, failed to establish dose differentiation and statistically significant efficacy. Parke-Davis did not

intend to publish the results of 945-177, nor did it intend to publish the combined results of 945-77 and 945-177.

144. Despite these negative trial results, the Promotion Enterprise continued to assert that Neurontin was an effective monotherapy for the treatment of epilepsy. For example, at the Jupiter Beach consultants meeting in August 1996, Dr. Harden and Dr. LeRoy gave presentations to attending physicians claiming that Neurontin was effective for monotherapy. Drs. Harden and Leroy misrepresented the results of Clinical Study 945-82, claiming that the study did not evidence a failure of Neurontin's efficacy and the lack of a dose response. Further, Dr. Leroy misrepresented that the Eastern European clinical trial was successful, when, in fact, the double blind codes of the study had not been broken, and patient recruitment had not been completed. Drs. Harden and Leroy could have only received information about the status of these unpublished clinical trials from Parke-Davis. Thus, while at the time of the Jupiter Beach meeting the only long-term clinical trials concerning Neurontin's use as monotherapy demonstrated that Neurontin was not effective for that use, physician attendees at Jupiter Beach came away with the message that Neurontin was effective as a monotherapy.

145. On September 16, 1996, Parke-Davis submitted a supplemental NDA to the FDA seeking approval of Neurontin as a monotherapy for partial seizures. On August 26, 1997, the FDA rejected Parke-Davis's application finding that the clinical trials performed did not establish effectiveness. Parke-Davis actively promoted Neurontin for monotherapy before it applied for FDA approval, before it received the FDA's response, and defiantly, after the FDA rejected its application for monotherapy. The Enterprise never mentioned the material fact that the FDA had rejected the application for monotherapy.

146. Representative events at which the Promotion Enterprise continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication included, but are not limited to, the following:

| **Event** | **Date** | **Location** |
|---|---|---|
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |
| Monotherapy Speakers Bureau Meeting at the La Quinta Resort | September 1997 | Palm Springs, CA |

147. Parke-Davis sales representatives routinely made false statements concerning Neurontin's safety, efficacy, effectiveness and usefulness as a monotherapy agent. Plaintiffs were only able to obtain evidence of such statements for a limited time period between 1995 and 1997, but are aware of "verbatim" reports that exist for the last several years. Upon information and belief, review of recent verbatim reports will demonstrate that similar statements were regularly made by the Defendants' sales forces from 1998 through 2004. Representative statements made to physicians include:

- In January 1997, a Parke-Davis sales representative falsely stated that Neurontin was "Excellent first line [monotherapy] or add-on prescription for seizures."
- In a 1998 event, Parke-Davis falsely stated that Neurontin "is effective as monotherapy."
- In October 1995, a Parke-Davis sales representative falsely stated that Neurontin's indicated use was "soon to be monotherapy."
- In June 1998, after the FDA had already rejected the monotherapy indication and Parke-Davis had abandoned pursuing approval for monotherapy, a Parke-Davis sales representative stated that Neurontin was "moving toward monotherapy indication in seizures."

- In a Parke-Davis marketing event later in 1998, Parke-Davis went so far as to state that Neurontin was "now approved as monotherapy for seizures."

### 11. False and Misleading Statements Regarding Dosages Above the FDA-Approved Maximum

148. Part of Defendants' strategy to increase sales of Neurontin was to convince physicians to prescribe it for adjunctive therapy at doses far exceeding the FDA-approved level, which was 900 to 1800 milligrams per day. At an advisory board meeting Parke-Davis admitted, "we therefore went on an aggressive campaign to try to convince the doctors to push the dose of Neurontin up into the 2400 to 3600 mg range."

149. Yet as early as December 30, 1994, Parke-Davis knew that an increased dosage of Neurontin does not mean that it is more effective because only a certain amount of the drug is actually absorbed by the body due to the manner it is excreted and the maximum levels that can accumulate.

150. As of November 1995, Parke-Davis knew that clinical trial 945-82 did not show a dose related response. Parke-Davis also knew that clinical trial 945-77 failed to establish dose differentiation and statistically significant efficacy. *See supra* ¶¶ 142–144. Such results were at odds with Parke-Davis's assertion that the larger the dose, the better the effect.

151. Despite these negative trial results, Defendants initiated a nationwide campaign to convince physicians to increase dosing to 2400 milligrams per day, 33% greater than the maximum dosage approved by the FDA as safe and effective.

152. In 1995 and 1996 Parke-Davis conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was in fact, a marketing ploy designed to induce neurologists to become comfortable prescribing Neurontin at a far higher dose than indicated in the FDA-approved labeling. While most clinical studies have a limited

number of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 physician "investigators" to enroll only a few patients each. The participating physicians were instructed to titrate their patients to higher-than-labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug. The STEPs study was designed to habituate physicians to place non-study patients on Neurontin on doses higher than those found effective in the clinical trials monitored by the FDA. Physicians who enrolled in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled. At the conclusion of the study, Parke-Davis offered each of the 1,200 investigators additional cash for each patient the doctor kept on Neurontin after the study ended.

153. Although Parke-Davis was routinely sponsoring programs that recommended that dosages be increased to as high as 4800 milligrams per day, Parke-Davis knew that it did not have sufficient toxicology data to prove that Neurontin was safe at dosages as high as even 3600 milligrams per day.

154. Nonetheless, during programs presented by the Promotion Enterprise, physician participants routinely stated that dosages above the maximum approved by the FDA increased Neurontin's efficacy. For example, during the migraine advisory board meeting, Dr. Rafferty, a preclinical researcher from Parke-Davis, falsely stated that: "The antiepileptic activity of gabapentin is quite dose dependent. Oh yeah." The negative findings of the monotherapy trial were not disclosed to the advisory board members.

155. At the consultants meeting in Jupiter Beach in April 1996, Dr. Longmire stated that: "most [patients] do better as you raise [the dose] higher." At the same presentation, and in other presentations, such as the consultants meeting at the Boston Ritz Carlton in May 1996, Dr. Longmire stated that the only reason a patient who was actually taking his medication and not

malingering would not receive any benefit from Neurontin was if he was not receiving a high enough dose. Neither Dr. Longmire nor the other Parke-Davis personnel present informed the physicians that Parke-Davis's own clinical trials established that there was no dose relationship.

156. At the consultants meeting at the Boston Ritz, Dr. Longmire also made false statements that: "the problem with Neurontin in terms of real trigeminal neuralgia is that it has to be titrated upward. And when I say 1500 milligrams, that's the target starting dose. There are colleagues in the Huntsville area who, I have people on 5400 with no side effects." This statement was misleading in that it (a) misrepresented that Neurontin was effective for trigeminal neuralgia at higher-than-approved doses, (b) did not disclose side effects reported to Parke-Davis at higher levels, (c) did not disclose the absence of toxicology data at these levels, (d) did not disclose there was no clinical data to support Neurontin's efficacy on trigeminal neuralgia, and (e) failed to disclose Parke-Davis's own clinical trials that questioned the existence of a dose relationship.

157. At the same consultants meeting in Boston, Dr. LeRoy stated that: "we found that clinical usage requires [daily dosages of] 2200, 3200, 3600, up to what I think … again, as I said earlier, a limit of about 4800 milligrams." This statement was not fair and balanced in that it did not disclose any contrary findings about the lack of dose-related response, including Parke-Davis's own outpatient study which failed to identify a dose response. Nor did this statement disclose that Parke-Davis had no toxicology data establishing safety at doses this high.

158. Notwithstanding the lack of toxicology data and clinical trial data supporting Neurontin's use at higher doses, physicians who attended these consultants meetings were convinced that they should be prescribing Neurontin at amounts in excess of its labeling. One physician noted "one of the main messages that I got out of the speakers [that doctors haven't

been pushing the dose up high enough]. (Inaudible) 4800 milligrams (Inaudible). And I've sort of gone to 24 and maybe a little higher and then stopped. To me, that was an important point (Inaudible) I'm not really pushing the drug enough."

159. As part of its monotherapy application to the FDA, Parke-Davis sought approval to increase the effective dose range to 3600 milligrams per day and to increase the maximum recommended dose to 4800 milligrams per day. On August 26, 1997, the FDA denied the application because there was no evidence that Neurontin was safe at such doses.

160. The FDA also informed Parke-Davis that if it did provide safety data, it could only obtain the labeling change if it further disclosed that "evidence from controlled trials fails to provide evidence that higher dose of Neurontin are more effective than those recommended."

161. Parke-Davis never disclosed that the FDA denied its request to increase the maximum approved dose of Neurontin, that the FDA had determined that Parke-Davis had not provided sufficient evidence of safety at higher doses, and that there was no clinical trial evidence that Neurontin was more effective at higher doses.

162. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater than 1800 milligrams per day, Parke-Davis continued to market Neurontin at higher doses without these disclosures. In addition to the events identified above, the Promotion Enterprise presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 milligrams per day. These events include, but are not limited to, the following:

| **Event** | **Date** | **Location** |
|---|---|---|
| Advisory Board on Neurontin at the Royal Sonesta | February 4-6, 2000 | New Orleans, LA |
| Merritt-Putnam Speakers Bureau | March 24-26, 2000 | Beverly Hills, CA |

| Event | Date | Location |
|---|---|---|
| Current Perspectives in the Understanding of Neurobehavioral Disorders at the Four Seasons Regent Beverly Wilshire | | |
| Advisory Board Meeting at the Hyatt Regency Hotel | March 29, 2000 | San Antonio, TX |

**12. False and Misleading Statements Regarding the Lack of Side Effects**

163. Parke-Davis knew that there was a dose relationship between Neurontin and side effects. Clinical trial 945-77 demonstrated that patients were three times more likely to have side effects at 1800 milligrams per day than at 900 milligrams per day.

164. Parke-Davis was aware that the January 1996 edition of Epilepsy reported behavioral side effects of gabapentin in seven children who received Neurontin as adjunctive therapy. The most troublesome behaviors were tantrums, aggression towards others, hyperactivity and defiance.

165. Parke-Davis knew as of November 19, 1996 that high doses of gabapentin could lead to weight gain.

166. Parke-Davis also knew that similar to other anti-epileptic drugs, patients on high doses of Neurontin had to be titrated down, or else they would suffer withdrawal symptom side effects.

167. At numerous events presented by the Promotion Enterprise, physician participants informed physician attendees that Neurontin use at high levels did not cause side effects. For example, at the Jupiter Beach consultants meeting in April 1996, Dr. Schachter stated: "Well, I don't think there's any data suggesting that there's any withdrawal syndrome from Neurontin at this point." Parke-Davis was aware, however, of at least anecdotal reports of withdrawal

syndrome and that Neurontin patients had to be tapered off Neurontin in much the same manner that they titrated up, but physician attendees were not informed of this information.

168. Similarly, at the Boston Ritz Carlton consultants meeting in May 1996, Dr. Longmire falsely stated that adverse reactions tend to be idiosyncratic, and that they did not seem to be dose-dependent. Again, the physician attendees were not informed of the medical evidence in Parke-Davis's possession that side effects were indeed dose responsive. Defendants' failure to provide this information made any prior representations about Neurontin's propensity to induce side effects at dosages over 1800 milligrams day false and misleading.

**F. Alternative Parallel Enterprises**

169. As part of their fraudulent marketing scheme, and alternatively to the Promotion Enterprise, Defendants established individual parallel enterprises consisting of the Defendants, each individual vendor participant and the participant physicians. These alternative parallel enterprises are as follows:

a. The Cline Davis Enterprise. Defendants, Cline Davis and the physician participants formed the Cline Davis Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 45 through 51 are incorporated herein by reference.

b. The Physicians World Enterprise. Defendants, Physicians World and the physician participants formed the Physicians World Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 52 through 62 are incorporated herein by reference.

c. The Sudler & Hennessey Enterprise. Defendants, Sudler & Hennessey and the physician participants formed the Sudler & Hennessey Enterprise with the goal and purpose of

promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 63 through 68 are incorporated herein by reference.

d. The MEDED/MEDCON Enterprise. Defendants, MEDED/MEDCON and the physician participants formed the MEDED/MEDCON Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 69 through 74 are incorporated herein by reference.

e. The MES Enterprise. Defendants, MES and the physician participants formed the MES Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 75 through 81 are incorporated herein by reference.

f. The HCC Enterprise. Defendants, HCC and the physician participants formed the HHC Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraph 82 are incorporated herein by reference.

g. The AMM/Adelphi Enterprise. Defendants, AMM/Adelphie and the physician participants formed the AMM/Adelphie Enterprise with the goal and purpose of promoting Neurontin for uses for which it was not proven to be safe, medically efficacious, effective or useful. The facts and allegations set forth in paragraphs 83 through 86 are incorporated herein by reference.

**G. The Continuing Impact of Defendants' Fraudulent Off-Label Promotion**

170. As a result of the intense and prolonged fraudulent scheme described above, the medical literature and usage practices relating to Neurontin have been severely contaminated by

years of false and misleading information regarding the scientific, medical and clinical data relating to the safety, medical efficacy, effectiveness and usefulness of Neurontin for conditions other than as adjunctive therapy for adult epilepsy at specified dosages. Based on this false information, physicians continue to prescribe, and Plaintiffs continue to pay for, Neurontin to treat off-label uses for which there is no reliable scientific support.

171. Upon information and belief, Pfizer has routinely marketed Neurontin for off-label indications up until May of 2004. The staggering growth of Neurontin sales highlights this continuing course of conduct. From 1995 to 2003, Neurontin's sales soared from $97.5 million to nearly $2.7 billion. With no reliable scientific studies supporting off-label uses, and with at least 90% of all prescriptions for Neurontin written for such uses, it is reasonable to infer that this explosion in sales stems from illegal past and continuing promotional efforts by Defendants. Physicians have and continue to prescribe Neurontin to tens of thousands of patients who are in need of effective treatments.

172. Furthermore, although Neurontin is prescribed for many off-label indications, since 1999 the types of off-label usage continue to be weighted in the precise areas where Defendants focused their unlawful marketing efforts, *i.e.*, as treatments for bipolar disorder, peripheral neuropathy and migraines.

173. A July 1, 2002, letter from Dr. Lisa Stockbridge of the Department of Health & Human Services ("HHS") confirms that Defendants continued as of that date to engage in wrongful off-label promotional efforts. Dr. Stockbridge notified Pfizer that certain of its marketing practices are "in violation of the Federal Food, Drug and Cosmetic Act . . . because [Pfizer] makes representations about Neurontin that are false and misleading." In particular, HHS determined that Pfizer's marketing materials suggested that the mechanism of action of Neurontin

had been established, when it was not appropriate to make such a claim. The FDA also stated that Pfizer materials suggested that Neurontin could be used as monotherapy, when it was only appropriate to indicate Neurontin as adjunctive therapy in the treatment of partial seizures. HHS determined that Pfizer's marketing materials were misleading and ordered immediate discontinuation of their use. The marketing practices found to be misleading by HHS in 2002 are similar to, or the same as, those routinely engaged in by the Promotion Enterprise under Parke-Davis's, and then Pfizer's, direction.

174. As of the third quarter of 2002, there was no basis in the published scientific literature for the use of Neurontin to treat the following conditions: alcohol detoxification/alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder/attention deficit and hyperactivity disorder, behavior problems-dementia related, behavior dyscontrol, dipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, diabetic peripheral neuropathy, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HIV-related neuropathy, nicotine withdrawal, nystagmus, obsessive-compulsive disorder, orthostatis tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizures-monotherapy, partial seizures-refractory, phantom limb syndrome, postherpetic neuralgia, restless leg syndrome, trigeminal neuralgia, seizures - acute intermittent prophyria, seizures - brain tumor-induced, seizures - clozapine-induced, seizures - generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than the partial seizures-

adjunctive therapy, partial seizures-pediatric, postherpetic neuralgia and diabetic peripheral neuropathy.

175. With the absence of scientific evidence to support the use of Neurontin to treat the forgoing conditions, the only explanation for the dramatic increase in Neurontin sales from 1994 through the present is the effectiveness of Defendants' marketing scheme flagrantly and fraudulently promoting Neurontin for these off-label uses.

**H. Related Government Actions**

176. As noted above, Dr. Franklin initiated a *qui tam* action on behalf of the United States against Warner-Lambert in 1996. He alleged two counts of false claims caused by the knowing promotion of prescription sales of Neurontin ineligible for Medicaid reimbursement and caused by the payment of kickbacks in violation of the Medicaid anti-kickback provisions, 31 U.S.C. § 3729. The federal court unsealed the original complaint in the *qui tam* action in January 2000. In May 2002, the Court unsealed the *qui tam* amended complaint, which for the first time, contained details of Defendants' off-label promotion and fraudulent marketing scheme. In April 2003, Dr. Franklin filed an opposition to a motion for summary judgment in the *qui tam* action which unsealed numerous documents revealing the existence and operation of Defendants' fraudulent marketing practices and the Promotion Enterprise.

177. Based on the conduct alleged in the *qui tam* action, the State Attorneys' General commenced a lawsuit against Warner-Lambert alleging violations of state consumer protection laws and the U.S. Department of Justice filed a criminal information against Warner-Lambert. On May 13, 2004, Warner-Lambert announced its agreement to plead guilty and pay more than $430 million to resolve the criminal charges and civil liabilities in connection with Parke-Davis's illegal and fraudulent promotion of unapproved uses for Neurontin. According to the Department of Justice Press Release, "[a]s a consequence of the unlawful promotion scheme, patients who

received the drug for unapproved and unproven uses had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Warner-Lambert." Dept. of Justice Press Release, May 13, 2004.

178. The Assurance of Voluntary Compliance entered into between the State Attorneys General and Warner-Lambert explicitly provided that claims brought by individual consumers and entities were excluded from the settlement.

## V. FRAUDULENT CONCEALMENT AND TOLLING OF STATUTES OF LIMITATIONS

179. Defendants' fraudulent marketing scheme depended on their concealing their involvement in off-label promotion of Neurontin. Indeed, the Promotion Enterprise was created precisely to make it appear to the public that the Defendants did not have a hand in any discussions or promotion of off-label use. Additionally, as described above, Defendants had the Promotion Enterprise perform off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles and medical education events. Also as described above, Defendants' involvement was hidden because Defendants hid their financial connections with the physician participants and used the vendor participants as payment intermediaries. These activities and others described above concealed Defendants' fraudulent promotional activities and Plaintiffs could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Indeed, much of the scheme to this day remains concealed by Defendants.

180. The earliest Plaintiffs could have reasonably become aware of the fraudulent marketing scheme was May 2003, when the details of Defendants' interactions with the other participants in the Promotion Enterprise were disclosed through the filing of previously sealed

materials in opposition to Defendants' motion for summary judgment in the *qui tam* action. Alternatively, Plaintiffs in the exercise of reasonable diligence could not have learned of the fraudulent marketing scheme until some of the details were disclosed when the amended complaint was unsealed in the *qui tam* case in May 2002.

181. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these clams, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

## VI. DEFENDANTS' MOTIVE

182. Defendants' motive in creating and operating the fraudulent scheme and RICO Enterprises described herein was to fraudulently obtain significant additional revenues from the marketing and sale of Neurontin.

183. The fraudulent scheme was designed to, and did, cause Plaintiffs to pay for Neurontin prescriptions to treat conditions for which the drug is not proven to be medically safe, efficacious, effective or useful. Plaintiffs paid millions of dollars for Neurontin that would not have been paid absent the fraudulent scheme.

## VII. USE OF THE MAILS AND WIRES

184. Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed physicians, medical marketing firms and victims across the country.

185. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications, including:

a. marketing and advertising materials about the off-label uses of Neurontin for which the drug is not proven to be safe, medically efficacious, effective and useful, such materials being sent to doctors across the country;

b. communications, including financial payments, with the vendor and physician participants discussing and relating to the publication of articles misrepresenting off-label uses of Neurontin;

c. communications with the vendor and physician participants that fraudulently misrepresented that Neurontin was scientifically proven to be safe, medically efficacious, effective and useful for off-label uses;

d. communications with health insurers and patients, including Plaintiffs, inducing payments for Neurontin to be made based on misrepresentations concerning the safety, efficacy, effectiveness and usefulness of Neurontin; and

e. receiving the proceeds of the Defendants' improper scheme.

186. In addition, Defendants' corporate headquarters have communicated by United States mail, telephone and facsimile with various local district managers, medical liaisons and pharmaceutical representatives in furtherance of Defendants' scheme.

## VIII. SCOPE OF THE ALLEGATIONS

### A. Time

187. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Neurontin, occurred between December 30, 1993, the date that the FDA approved the marketing of Neurontin, and the present day. The conduct and patterns of conduct alleged

herein occurred and continued to occur well after the consummation of the merger between Pfizer and Warner-Lambert in June 2000.

**B. Geographic Scope**

188. The conduct and patterns of conduct alleged herein, relating to the sale and marketing of Neurontin, took place throughout the entire United States and District of Columbia, as well as various other territories and foreign countries. Although Defendants' upper-level management has been based in Morris Plains, New Jersey or New York, New York, the actual sales and marketing activities described herein were executed principally through Defendants Customer Business Unit ("CBU") system, a network of regional sales division that covered the entire country.

## IX. CLAIMS FOR RELIEF

**FIRST CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The Promotion Enterprise)**

189. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

190. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

191. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) the vendor participants, Cline Davis, Physicians World, Sudler & Hennessey, MEDED, MES, HCC and AMM/Adelphi, and (iii) the physician participants as set forth in paragraph 95 ("Promotion Enterprise"). The Promotion Enterprise is an ongoing organization that functions as a continuing unit. The

Promotion Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Promotion Enterprise.

192. The Promotion Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

193. Defendants have conducted and participated in the affairs of the Promotion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

194. The Promotion Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

195. Defendants exerted control over the Promotion Enterprise, and Defendants participated in the operation or management of the affairs of the Promotion Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the Promotion Enterprise at each seminar, event and presentation, and in the publications by the vendor and physician participants, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the Promotion Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation, and selected and approved each physician "author" for the published materials propounded by the Promotion Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the Promotion Enterprise.

e. Defendants paid the vendor and the physician participants for their participation in the Promotion Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the Promotion Enterprise.

196. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

197. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such

racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

198. The pattern of racketeering activity alleged herein and the Promotion Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Promotion Enterprise.

199. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

200. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

201. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**SECOND CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The Cline Davis Enterprise)**

202. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

203. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

204. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) Cline Davis and (iii)

the physician participants as set forth in paragraph 95 ("Cline Davis Enterprise"). The Cline Davis Enterprise is an ongoing organization that functions as a continuing unit. The Cline Davis Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Cline Davis Enterprise.

205. The Cline Davis Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

206. Defendants have conducted and participated in the affairs of the Cline Davis Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

207. The Cline Davis Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

208. Defendants exerted control over the Cline Davis Enterprise, and Defendants participated in the operation or management of the affairs of the Cline Davis Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by Cline Davis, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the Cline Davis Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the Cline Davis Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the Cline Davis Enterprise.

e. Defendants paid Cline Davis and the physician participants for their participation in the Cline Davis Enterprise and split budget overrun with Cline Davis for activities furthering the Cline Davis Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the Cline Davis Enterprise, and permitted Cline Davis to place its own employees on Defendants' Extended Neurontin Disease Team.

209. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal,

information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

210. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

211. The pattern of racketeering activity alleged herein and the Cline Davis Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Cline Davis Enterprise.

212. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

213. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

214. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

## THIRD CLAIM FOR RELIEF
**Violation of 18 U.S.C. § 1962(c) (The Physicians World Enterprise)**

215. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

216. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

217. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) Physicians World and (iii) the physician participants as set forth in paragraph 95 ("Physicians World Enterprise"). The Physicians World Enterprise is an ongoing organization that functions as a continuing unit. The Physicians World Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Physicians World Enterprise.

218. The Physicians World Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

219. Defendants have conducted and participated in the affairs of the Physicians World Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

220. The Physicians World Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

221. Defendants exerted control over the Physicians World Enterprise, and Defendants participated in the operation or management of the affairs of the Physicians World Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by Physicians World, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the Physicians World Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the Physicians World Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the Physicians World Enterprise.

e. Defendants paid Physicians World and the physician participants for their participation in the Physicians World Enterprise.

f. Defendants formed a strategic partnership with Physicians World in order to carry out the activities of the Physicians World Enterprise. This partnership included the commingling of employees among Defendants and Physicians World.

g. Defendants placed their own employees and agents in positions of authority and control in the Physicians World Enterprise.

222. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not

scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

223. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

224. The pattern of racketeering activity alleged herein and the Physicians World Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Physicians World Enterprise.

225. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

226. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

227. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**FOURTH CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The Sudler & Hennessey Enterprise)**

228. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

229. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

230. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) Sudler & Hennessey and (iii) the physician participants as set forth in paragraph 95 ("Sudler & Hennessey Enterprise"). The Sudler & Hennessey Enterprise is an ongoing organization that functions as a continuing unit. The Sudler & Hennessey Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Sudler & Hennessey Enterprise.

231. The Sudler & Hennessey Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

232. Defendants have conducted and participated in the affairs of the Sudler & Hennessey Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C.

§§ 1961(1) and 1961(5), that includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

233. The Sudler & Hennessey Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

234. Defendants exerted control over the Sudler & Hennessey Enterprise, and Defendants participated in the operation or management of the affairs of the Sudler & Hennessey Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by Sudler & Hennessey, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the Sudler & Hennessey Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the Sudler & Hennessey Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by Sudler & Hennessey.

e. Defendants paid Sudler & Hennessey and the physician participants for their participation in the Sudler & Hennessey Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the Sudler & Hennessey Enterprise.

235. As detailed above, Defendants' fraudulent scheme consisted of, inter alia: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe and efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

236. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the Plaintiffs' property.

237. The pattern of racketeering activity alleged herein and the Sudler & Hennessey Enterprise are separate and distinct from each other. Defendants engaged in a pattern of

racketeering activity alleged herein for the purpose of conducting the affairs of the Sudler & Hennessey Enterprise.

238. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

239. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

240. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**FIFTH CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The MEDED/MEDCON Enterprise)**

241. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

242. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

243. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) MEDED/MEDCON and (iii) the physician participants as set forth in paragraph 95 ("MEDED/MEDCON Enterprise"). The MEDED/MEDCON Enterprise is an ongoing organization that functions as a continuing unit. The MEDED/MEDCON Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the MEDED/MEDCON Enterprise.

244. The MEDED/MEDCON Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

245. Defendants have conducted and participated in the affairs of the MEDED/MEDCON Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), that includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

246. The MEDED/MEDCON Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

247. Defendants exerted control over the MEDED/MEDCON Enterprise, and Defendants participated in the operation or management of the affairs of the MEDED/MEDCON Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by MEDED/MEDCON, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the MEDED/MEDCON Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved

each physician "author" for the published materials propounded by the MEDED/MEDCON Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the MEDED/MEDCON Enterprise.

e. Defendants paid MEDED/MEDCON and the physician participants for their participation in the MEDED/MEDCON Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the MEDED/MEDCON Enterprise.

248. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

249. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe and efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants

and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the Plaintiffs' property.

250. The pattern of racketeering activity alleged herein and the MEDED/MEDCON Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the MEDED/MEDCON Enterprise.

251. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

252. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

253. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**SIXTH CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The MES Enterprise)**

254. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

255. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

256. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) MES and (iii) the

physician participants as set forth in paragraph 95 ("MES Enterprise"). The MES Enterprise is an ongoing organization that functions as a continuing unit. The MES Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the MES Enterprise.

257. The MES Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

258. Defendants have conducted and participated in the affairs of the MES Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), that includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

259. The MES Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

260. Defendants exerted control over the MES Enterprise, and Defendants participated in the operation or management of the affairs of the MES Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by MES, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the MES Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the MES Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the MES Enterprise.

e. Defendants paid MES and the physician participants for their participation in the MES Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the MES Enterprise.

261. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

262. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

263. The pattern of racketeering activity alleged herein and the MES Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the MES Enterprise.

264. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

265. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

266. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

## SEVENTH CLAIM FOR RELIEF
**Violation of 18 U.S.C. § 1962(c) (The HCC Enterprise)**

267. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

268. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

269. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) HCC and (iii) the physician participants as set forth in paragraph 95 ("HCC Enterprise"). The HCC Enterprise is an ongoing organization that functions as a continuing unit. The HCC Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the HCC Enterprise.

270. The HCC Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

271. Defendants have conducted and participated in the affairs of the HCC Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), that includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

272. The HCC Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

273. Defendants exerted control over the HCC Enterprise, and Defendants participated in the operation or management of the affairs of the HCC Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by HCC, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the HCC Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the HCC Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the HCC Enterprise.

e. Defendants paid HCC and the physician participants for their participation in the HCC Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the HCC Enterprise.

274. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false

information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

275. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiffs' property.

276. The pattern of racketeering activity alleged herein and the HCC Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the HCC Enterprise.

277. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

278. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

279. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**EIGHTH CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(c) (The AMM/Adelphi Enterprise)**

280. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

281. In the alternative, Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

282. The enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Defendants, including their employees and agents, (ii) AMM/Adelphi and (iii) the physician participants as set forth in paragraph 95 ("AMM/Adelphi Enterprise"). The AMM/Adelphi Enterprise is an ongoing organization that functions as a continuing unit. The AMM/Adelphi Enterprise was created and used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the AMM/Adelphi Enterprise.

283. The AMM/Adelphi Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Neurontin for off-label uses and earning profits therefrom.

284. Defendants have conducted and participated in the affairs of the AMM/Adelphi Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), that includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described above.

285. The AMM/Adelphi Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased or provided Neurontin to thousands of entities and individuals throughout the United States.

286. Defendants exerted control over the AMM/Adelphi Enterprise, and Defendants participated in the operation or management of the affairs of the AMM/Adelphi Enterprise, through a variety of actions including the following:

a. Defendants controlled the content of the messages being delivered by the physician participants at each seminar, event and presentation sponsored by AMM/Adelphi, including the misinformation and false statements concerning the safety, efficacy, effectiveness and usefulness of Neurontin for off-label uses.

b. Defendants controlled the stream of information disseminated by the AMM/Adelphi Enterprise concerning Neurontin by ensuring that only favorable results were published and disclosed and unfavorable results were suppressed.

c. Defendants selected and approved which physician participant(s) would deliver the off-label message at each seminar, event and presentation and selected and approved each physician "author" for the published materials propounded by the AMM/Adelphi Enterprise.

d. Defendants selected who attended each seminar, event and presentation sponsored by the AMM/Adelphi Enterprise.

e. Defendants paid AMM/Adelphi and the physician participants for their participation in the AMM/Adelphi Enterprise.

f. Defendants placed their own employees and agents in positions of authority and control in the AMM/Adelphi Enterprise.

287. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Neurontin was safe and effective so that Plaintiffs paid for this drug to treat symptoms for which it was not scientifically proven to be safe, efficacious, effective and useful; (b) presenting seminars and

events misrepresenting off-label uses for Neurontin for which Defendants' knew were not proven to be scientifically safe, efficacious, effective and useful to physician attendees and other healthcare providers; (c) publishing or causing to have published materials containing false information upon which physicians and Plaintiffs relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses; and (d) actively concealing, and causing others to conceal, information about the true safety, efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

288. Defendants' scheme and the above described racketeering activities amounted to a common course of conduct intended to cause Plaintiffs and others to pay for Neurontin to treat conditions for which it was not proven to be safe, efficacious, effective and useful. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to the Plaintiffs' property.

289. The pattern of racketeering activity alleged herein and the AMM/Adelphi Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the AMM/Adelphi Enterprise.

290. Plaintiffs have been injured in their property by reason of these violations in that Plaintiffs have made millions of dollars in payments for Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

291. Plaintiffs' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

292. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**NINTH CLAIM FOR RELIEF**
**Violation of 18 U.S.C. § 1962(d) by Conspiring to Violate 18 U.S.C. § 1962(c)**

293. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

294. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

295. Defendants have violated section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the section 1962(c) Enterprises described previously through a pattern of racketeering activity.

296. As demonstrated in detail above, Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs of money.

297. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

298. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. §§ 1962(c),

Plaintiffs have been and are continuing to be injured in their business or property as set forth more fully above.

299. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346; and

c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346.

300. Defendants have sought to and have engaged in the violations of the above federal laws and the effects thereof detailed above are continuing and will continue unless injunctive relief prohibiting Defendants' illegal acts constituting a pattern of racketeering activity is fashioned and imposed by the Court.

**TENTH CLAIM FOR RELIEF**
**Violations of the California Unfair Competition Law**
**Cal. Bus. & Prof. Code § 17200**

301. Plaintiffs repeat and reallege each of the preceding paragraphs, as if fully set forth herein.

302. Defendants engaged in unfair competition in knowing violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.*, when Defendants knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness and usefulness of Neurontin to treat non-FDA approved uses.

303. Defendants' unfair and deceptive acts were specifically designed to induce Plaintiffs to pay for Neurontin for off-label and non-medically safe, effective and useful uses.

304. As a result of Defendants' violations of Business and Professions Code section 17200, Defendants have been unjustly enriched at the expense of Plaintiffs. Absent Defendants' unlawful, fraudulent and deceptive conduct, Plaintiffs would not have paid for Neurontin to treat conditions for which the drug was not FDA approved and not medically safe, efficacious, effective and useful.

305. The acts, omissions, misrepresentations, practices and non-disclosures of Defendants, as alleged herein, constituted and constitute a continuous course of conduct of unfair competition by means of unfair, unconscionable, unlawful and/or fraudulent business acts or practices within the meaning of California Business and Professions Code section 17200 *et seq.*, including, but not limited to the following:

a. violations of the RICO statute, 18 U.S.C. § 1962(c) and (d), as set forth above;

b. violations of the consumer protection statutes of the remaining forty-nine states, the District of Columbia and the Commonwealth of Puerto Rico, as set forth below;

c. Defendants' acts and business practices as described above are otherwise unfair, unconscionable, unlawful and fraudulent, whether or not in violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq*., the RICO statute, 18 U.S.C. § 1962(c) and (d), or the consumer protection statutes of the remaining states, the District of Columbia and Puerto Rico; and

d. Defendants' acts and practices are fraudulent or deceptive within the meaning of California Business and Professions Code section 17200 *et seq.*

306. The unlawful and unfair business practices of Defendants have injured and present a continuing threat of injury to Plaintiffs in that Defendants' conduct has caused Plaintiffs to pay for Neurontin to treat conditions for which the drug was not FDA approved and not medically safe, efficacious, effective and useful. Further, Defendants' fraudulent marketing scheme has made it likely that Plaintiffs, and other third-party payors, have been and will continue to be deceived with respect to the safety, efficacy, effectiveness and usefulness of Neurontin to treat off-label conditions.

307. As alleged herein, Defendants have been unjustly enriched as a result of their unfair competition. Plaintiffs are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Defendants as a result of such business acts or practices, pursuant to California Business and Professions Code sections 17203 and 17204.

## ELEVENTH CLAIM FOR RELIEF
### Violations of the Consumer Protection Statutes of the Remaining 49 States, The District of Columbia and the Commonwealth of Puerto Rico

308. Plaintiffs repeat and reallege each of the preceding paragraphs, as if fully set forth herein.

309. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in knowing violation of any and all state consumer protection statutes when Defendants knowingly and intentionally misrepresented the medical safety, efficacy, effectiveness and usefulness of Neurontin to treat non-FDA approved uses.

310. Defendants' unfair or deceptive acts or practices were specifically designed to induce Plaintiffs to pay for Neurontin for off-label and non-medically safe, effective and useful uses.

311. Defendants have violated the consumer protection statutes of the remaining forty-nine states, the District of Columbia and the Commonwealth of Puerto Rico, as follows:

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 50511, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1 b, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.0 10, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices m violation of N.Y. Gen. Bus. Law § 349 *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices m violation of Ohio Rev. Stat. § 1345.0 1, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 2451, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendants have engaged in unfair competition or unfair or deceptive acts or practice in violation of 23 L.P.R.A. § 1001 *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

312. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs have suffered damages in an amount to be proved at trial by paying for Neurontin to treat conditions for which the drug was not FDA approved and not medically safe, efficacious, effective and useful.

## TWELTH CLAIM FOR RELIEF
**Insurance Fraud - Violation of 18 Pa. C.S. § 4117**

313. Plaintiffs repeat and reallege each of the preceding paragraphs, as if fully set forth herein.

314. The Pennsylvania Insurance Fraud Statute, 18 Pa. C.S. § 4117(a)(2), provides that a person commits an offense if he or she:

Knowingly and with the intent to defraud any insurer or self-

> insured, presents or causes to be presented to any insurer or self-insured any statement forming a part of, or in support of a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim.

315. Defendants knowingly and with intent to defraud have engaged in a pattern of causing to be presented to Plaintiffs false, incomplete, and misleading insurance claim information.

316. Defendants' fraudulent schemes consisted of: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiffs and their members were unaware that they were paying Neurontin claims for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective and useful so that Plaintiffs and their members unwittingly paid for the drug to treat symptoms for which it was not scientifically proven to be safe, effective or useful; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiffs and their members relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious, effective or useful; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy, effectiveness and usefulness of Neurontin to treat conditions for which it had not been approved by the FDA.

317. Defendants' schemes discussed in the previous paragraphs were calculated to ensure that Plaintiffs would be over-billed for Neurontin.

318. Each of the fraudulent acts detailed above constitutes "Insurance Fraud" within the meaning of 18 Pa. C.S. § 4117(a). Collectively, these violations constitute a pattern of insurance fraud within the meaning of 18 Pa. C.S. § 4117(g).

319. Much of the wrongful, deceptive and unfair conduct detailed in this Complaint took place in Pennsylvania and/or caused injury to Plaintiffs and others in Pennsylvania.

320. The above-described pattern of insurance fraud amounted to a common course of conduct intended to deceive Plaintiffs. Each such fraudulent act was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs. Defendants' fraudulent activities were and are part of its regular way of conducting its ongoing business, and constitute a present and continuing threat to the property of Plaintiffs.

321. By reason of the foregoing, and as a proximate cause of said pattern of fraudulent activity and its acts committed in furtherance thereof, Plaintiffs have suffered grievous injury and have been damaged, as alleged herein.

322. By virtue of these violations of 18 Pa. C.S. § 4117, Defendants are liable to each Plaintiff for three times the damages sustained, plus investigation expenses, costs of this suit, and reasonable attorneys' fees and expenses.

## THIRTEENTH CLAIM FOR RELIEF
**Restitution/Disgorgement for Unjust Enrichment**

323. Plaintiffs repeat and reallege each of the preceding paragraphs, as if fully set forth herein.

324. Plaintiffs have conferred on Defendants' benefits in the form of payments for Neurontin that would not have been made had Defendants not engaged in the wrongful acts and practices alleged herein.

325. Retention of the payments and other benefits by Defendants would be inequitable and unjust in this case because Defendants' deceptive conduct caused Plaintiffs to pay for Neurontin when they otherwise would not have had to do so.

326. In fairness, under the equitable doctrine of unjust enrichment, Defendants should be required to disgorge to Plaintiffs the revenues or profits Defendants earned from their improper sales of Neurontin to Plaintiffs' members.

## X. DEMAND FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, as follows:

a. On Plaintiffs' First through Ninth Claims for Relief, three times the damages each Plaintiff has sustained as a result of Defendants' conduct, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees.

b. On Plaintiffs' Tenth Claim for Relief, an award to each Plaintiff of the disgorgement of all sums improperly received by Defendants, plus costs of this suit, and reasonable attorneys' fees and expenses;

c. On Plaintiffs' Eleventh Claim for Relief, an award to each Plaintiff of the maximum damages allowable under such statutes;

d. On Plaintiffs' Twelfth Claim for Relief, an award to each Plaintiff of three times the damages sustained as a result of Defendants' conduct, plus investigation expenses, costs of this suit, and reasonable attorneys' fees and expenses;

e. On Plaintiffs' Thirteenth Claim for Relief, an award to each Plaintiff of disgorgement of all sums improperly received by Defendants;

f. An award of prejudgment interest in the maximum amount allowable by law;

g. An award to Plaintiffs of their costs and expenses in this litigation and reasonable attorneys' and expert fees and expenses; and

h. An award to Plaintiffs of such other and further relief as may be just and proper under the circumstances.

**DEMAND FOR A JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b), each Plaintiff demands a trial by jury on all issues so triable.

Dated: February 1, 2005

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